Exhibit B

PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C. 20436

In the Matter of **CERTAIN BOTULINUM TOXIN PRODUCTS, PROCESSES FOR MANUFACTURING OR RELATING TO SAME AND CERTAIN PRODUCTS CONTAINING SAME**	**Inv. No. 337-TA-1145**

FINAL INITIAL DETERMINATION

Administrative Law Judge David P. Shaw

Pursuant to the notice of investigation, 84 Fed. Reg. 8112 (Mar. 6, 2019), this is the final initial determination on violation in *Certain Botulinum Toxin Products, Processes for Manufacturing or Relating to Same and Certain Products Containing Same*, United States International Trade Commission Investigation No. 337-TA-1145.

It is held that a violation of section 337 (19 U.S.C. § 1337) has occurred by reason of misappropriation of trade secrets.

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The following abbreviations may be used in this Initial Determination:

ALJ	-	Administrative Law Judge
CDX	-	Complainants' Demonstrative Exhibit
CPX	-	Complainants' Physical Exhibit
CX	-	Complainants' Exhibit
Dep.	-	Deposition
EDIS	-	Electronic Document Imaging System
JPX	-	Joint Physical Exhibit
JX	-	Joint Exhibit
P.H.	-	Prehearing
RDX	-	Respondents' Demonstrative Exhibit
RPX	-	Respondents' Physical Exhibit
RWS	-	Rebuttal Witness Statement
RX	-	Respondents' Exhibit
Tr.	-	Transcript
WS	-	Witness Statement

I. Background

A. Institution of the Investigation; Procedural History

By publication of a notice in the *Federal Register* on March 6, 2019, pursuant to section 337 of the Tariff Act of 1930, as amended, the Commission instituted this investigation to determine:

> [W]hether there is a violation of subsection (a)(1)(A) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of misappropriation of trade secrets, the threat or effect of which is to destroy or substantially injure a domestic industry in the United States.

84 Fed. Reg. 8112 (Mar. 6, 2019).

Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 C.F.R. § 210.10(b)(1):

> [T]he plain language description of the accused products or category of accused products, which defines the scope of the investigation, is botulinum neurotoxin products manufactured by Daewoong Pharmaceuticals Co., Ltd., specifically: (1) DWP–450 (prabotulinumtoxinA), variously marketed under the brand names Nabota®, Jeuveau™ and other brand names; (2) products containing or derived from DWP–450; and (3) products containing or derived from the BTX strain assigned the high-risk pathogen control number 4–029–CBB–IS–001 by the Korean Centers for Disease Control and Prevention or the manufacturing process used to manufacture DWP–450.

Id.

The complainants are Medytox Inc. of Seoul, South Korea; Allergan plc of Dublin, Ireland; and Allergan, Inc. of Irvine, California. The named respondents are Daewoong Pharmaceuticals Co., Ltd. of Seoul, South Korea; and Evolus, Inc. of Irvine, California.

The Office of Unfair Import Investigations ("OUII" or "Staff") is a party to this investigation. *Id.*

The target date for completion of this investigation was initially set at approximately fourteen months and three weeks, *i.e.*, May 29, 2020. *See* Order No. 3 (Mar. 12, 2019). Accordingly, the original due date for the final initial determination on violation was January 29, 2020. *See id.* at 2.

On March 22, 2019, respondent Daewoong Pharmaceuticals Co., Ltd. ("Daewoong") filed a motion seeking summary determination that "all allegations in the Complaint as to the alleged theft of a bacterium be terminated from the Investigation, because the allegations cannot support a claim of trade secret misappropriation as a matter of law." The administrative law judge denied Daewoong's motion on May 7, 2019. *See* Order No. 7 (May 7, 2019).

On July 16, 2019, complainants and respondents jointly filed an unopposed motion requesting that the date for the hearing be extended by approximately two months because of ongoing expert discovery. On July 24, 2019, the administrative law judge issued an order that extended the deadline for the exchange of initial expert reports, and tentatively scheduled the evidentiary hearing to occur on February 4–7, 2020. *See* Order No. 19 (July 24, 2019). In accordance with the rescheduled evidentiary hearing, the administrative law judge issued an initial determination extending the target date to October 6, 2020, which is 19 months after institution of the investigation, (Order No. 23 (Aug. 16, 2019)), and the Commission determined not to review the initial determination, *see* Commission Decision Not to Review an Initial Determination Extending the Target Date (EDIS Doc. ID No. 688194) (Sept. 13, 2019).

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On November 15, 2019, respondents Daewoong and Evolus, Inc. ("Evolus") filed a motion for summary determination that "Allergan has no standing to pursue a claim that Daewoong misappropriated trade secrets belonging to Medytox." The administrative law judge denied respondents' motion on January 21, 2020. *See* Order No. 32 (Jan. 21, 2020).

On November 15, 2019, respondents Daewoong and Evolus filed a filed a motion for summary determination of "No Injury with Respect to Alleged Domestic Industry Product MT10109L." The administrative law judge denied respondents' motion on January 23, 2020. *See* Order No. 34 (Jan. 23, 2020).

On November 15, 2019, complainants Allergan plc and Allergan, Inc. (collectively, "Allergan"), and Medytox Inc. ("Medytox") filed a motion "for a partial summary determination that 'an industry in the United States' exists within the meaning of 19 U.S.C. § 1337(a)(1)(A) for botulinum neurotoxin products comprised of, separately and collectively, BOTOX® Cosmetic, BOTOX® therapeutic, and MT10109L ('Domestic Industry Products')." The administrative law judge denied complainants' motion on January 23, 2020. *See* Order No. 35 (Jan. 23, 2020).

A prehearing conference was held on February 4, 2020, with the evidentiary hearing in this investigation commencing immediately thereafter. Complainants Allergan and Medytox, respondents Daewoong and Evolus, and the Staff participated in the hearing. The hearing concluded on February 7, 2020. *See* Order No. 20 (Aug. 2, 2019); P.H. Tr. 1–35; Tr. 1–1006. The parties were requested to file post-hearing briefs not to exceed 300 pages in length, and to file reply briefs not to exceed 50 pages in length. P.H. Tr. 11.

On February 21, 2020, the parties filed a joint outline of the issues to be decided in the Final Initial Determination. *See* Parties' Joint Outline of the Issues to Be Decided ("Joint Outline") (EDIS Doc. ID No. 703193). On February 28, 2020, the parties filed a joint outline of the post-hearing briefs. *See* Parties' Joint Outline of Post-Hearing Briefs ("Joint Reply Outline") (EDIS Doc. ID No. 703716).

On July 1, 2020, the administrative law judge issued Order No. 42, an initial determination granting Motion Docket No. 1145-61 to amend the complaint and notice of investigation to reflect a corporate name change from Allergan plc to Allergan Limited. At this time, the initial determination is pending before the Commission.

B. Reopening the Record

Since the evidentiary hearing, the administrative law judge has ruled on five requests to reopen the record in this investigation,[1] with two additional requests pending.[2]

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[1] In Order No. 37, the administrative law judge granted a motion by complainants and respondents to admit certain exhibits and to permit the withdrawal of certain exhibits. In Order No. 38, the administrative law judge granted respondents' motion to reopen the record to receive RX-3564, containing certain financial information pertaining to Allergan plc and Allergan, Inc. In Order No. 39, the administrative law judge ruled on complainants' motion to reopen the record to admit certain deposition testimony and in the alternative to overrule respondents' objections to certain 30(b)(6)-style designations. The administrative law judge granted the motion by overruling the objections.

[2] On June 25, 2020, respondents filed another motion to reopen the record (Motion Docket No. 1145-62). On June 26, 2020, complainants filed a motion to reopen the record (Motion Docket No. 1145-63), which appears at least in part to relate to Motion No. 1145-62. Motion No. 1145-62 (to which complainants have responded) may ripen as late as the date on which this Final Initial Determination is filed, and Motion No. 1145-63 may ripen thereafter. Based on the content of the motions, complainants' response to Motion No. 1145-62, and the standards discussed in Order No. 40, the administrative law judge is not inclined to grant either motion. The administrative law judge will consider any response or responses to the motions that are filed and come to his attention before issuance of this Final Initial Determination. Unless granted, any ripe, pending motion is denied. *See* Section XII (Initial Determination and Order).

The fourth request to reopen the record was in the form of a motion (Motion Docket No. 1145-59) filed on April 29, 2020, by respondents Daewoong and Evolus to reopen the record to admit official Korean government documents reflecting criminal indictments and revocations of approval for certain products, and for judicial notice of such facts. The motion was opposed by complainants, and not opposed by the Staff. The administrative law judge granted the motion, admitted four documents, and provided the parties with the opportunity to file short briefs concerning the documents by June 3, 2020. *See* Order No. 40 at 3–4. Complainants, respondents and the Staff filed briefs.

On June 1, 2020, in view of the anticipated receipt of supplemental briefing on June 3, 2020, and exigencies related to the pandemic, the administrative law judge issued Order No. 41, an unreviewed initial determination extending the target date for completion of this investigation to November 6, 2020, *i.e.*, 20 months after institution of the investigation, thereby making the Final Initial Determination on violation due on July 6, 2020. *See* Order No. 41 at 3; Commission Decision Not to Review an Initial Determination Extending the Target Date (EDIS Doc. ID No. 713051) (June 19, 2020).

The fifth request to reopen the record was in the form of a motion (Motion Docket No. 1145-60) filed on June 3, 2020, by complainants. It was an unopposed motion to admit a Korean court ruling, and to take judicial notice of the same. The motion was granted. *See* Order No. 42 (June 22, 2020).

The four documents received through Order No. 40 were a press release by the office of a Korean prosecutor, and three statements (one press release and two documents pertaining to an alert) from the Korean Ministry of Food and Drug Safety. The document received through Order No. 42, as indicated above, is a court decision.

The documents received through Order No. 40 are not accorded any weight in this investigation. The actions recounted in the press release from the prosecutor's office, as expressly indicated in the press release, pertain to facts that have not been confirmed through trial. In addition, it is not clear that the action taken by the Ministry of Food and Drug Safety pertains to a product at issue in this investigation. Nor, especially in view of the court decision received through Order No. 42, is it clear that the action remains in effect.

C. The Parties

The complainants are Medytox Inc. of Seoul, South Korea; Allergan plc of Dublin, Ireland; and Allergan, Inc. of Irvine, California. Medytox is a limited liability corporation organized and existing under the laws of the Republic of Korea. *See* Complaint, ¶ 18. Medytox was founded in 2000 for the purpose of researching, developing, and manufacturing BTX[3] products. *See id.*, ¶ 19. In 2006, Medytox obtained approval from the Korean Ministry of Food and Drug Safety to sell the first BTX product developed in Korea, Meditoxin®. *See id.* Medytox later developed a liquid-form, animal-protein-free alternative BTX product called Innotox®, which is currently being sold in Korea. *See id.*, ¶ 20. In September 2013, pursuant to a supply and licensing agreement, Medytox licensed a formulation of Innotox® to Allergan for commercialization in the United States. *See id.* This formulation is known as MT10109L. *See id.*

[3] The terms "botulinum toxin (BTX)" and "botulinum neurotoxin (BoNT)" can be used interchangeably. Botulinum toxins are toxins expressed by the *C. botulinum* species of bacteria. The toxin has its lethal effect by preventing the release of a neurotransmitter to the muscle, thus causing paralysis. Inasmuch as the toxin acts on the nervous system, it is termed a neurotoxin. CX-0016C (Neervannan WS) at Q/A 9.

Complainant Allergan plc is a public limited company established under the laws of the Republic of Ireland.[4] *See id.*, ¶ 21. Allergan, Inc., a subsidiary of Allergan plc, is a corporation organized under the laws of the State of Delaware. *See id.* Allergan's products include BOTOX®, which is a product derived from the botulinum neurotoxin type A, which, in turn, is produced by processing the bacterium *Clostridium botulinum* ("*C. botulinum*"). *See id.*, ¶ 23. BOTOX® is used to treat a range of muscular conditions and for aesthetic purposes, such as treating glabellar lines, crow's feet, and forehead lines. *See id.* Allergan was the first company to launch a BTX product in the United States, achieving approval from the FDA for BOTOX® for therapeutic uses in 1989 and for aesthetic uses in 2002. *See id.*

Respondent Daewoong Pharmaceuticals Co., Ltd. is a limited liability company established under the laws of Korea. *See id.*, ¶ 25. Daewoong's business includes the manufacture and sale of pharmaceutical products and medical devices. *See id.*, ¶ 26.

Evolus is a public corporation organized under the laws of Delaware. *See id.*, ¶ 29. Evolus is a medical aesthetics company focused on delivering advanced aesthetic procedures and treatments to physicians and consumers. *See id.*, ¶ 30. Evolus has an exclusive licensing agreement with Daewoong regarding the accused products.

The Staff also remains a party to this investigation.

D. The Accused Products

The notice of investigation defined the accused products as "botulinum neurotoxin products manufactured by Daewoong Pharmaceuticals Co., Ltd., specifically:

[4] As indicated in Order No. 43 (which, as discussed in Section I.A (Background), is an initial determination pending before the Commission), following the acquisition of Allergan plc by AbbVie Inc., Allergan plc was changed to Allergan Limited.

(1) DWP-450 (prabotulinumtoxinA), variously marketed under the brand names Nabota, Jeuveau®, and other brand names; (2) products containing or derived from DWP-450; and (3) products containing or derived from the BTX strain assigned the high-risk pathogen control number 4-029-CBB-IS-001 by the Korean Centers for Disease Control and Prevention or the manufacturing process used to manufacture DWP-450." Notice of Institution of Investigation at 2 (Feb. 28, 2019).

1. DWP-450

DWP-450 is Daewoong's internal designation used to refer generally to Daewoong's BTX product, which is manufactured using the BTX strain assigned the Korean control number 4-029-CBB-IS-001 that is identified in the notice of investigation. *See* RX-3167C (KY Kim WS) at Q/A 15; CX-0972C.22-24 (DW Rog. Resp. No. 15); CX-0973C.21-23 (DW Rog. Resp. No. 14). DWP-450-derived products are sold in South Korea under the brand name Nabota, in the United States under the brand name Jeuveau®, and in Canada and Europe under the brand name Nuceiva. Nabota and Jeuveau® contain the same drug substance, *i.e.*, active pharmaceutical ingredient. RX-3167C (KY Kim WS) at Q/A 20.

2. Jeuveau®

Jeuveau® is the brand name for the formulation of DWP-450 that has received U.S. FDA approval and is on sale in the United States. *See* RX-3167C (KY Kim WS) at Q/A 15-20; RX-3162C (Moatazedi WS) at Q/A 15–16. Jeuveau® is a 900 kilodalton product that is indicated for the treatment of glabellar lines. Mulhern Tr. 928. It is manufactured by Daewoong and sold in the United States by Evolus. RX-3162C (Moatazedi WS) at Q/A 75; Moatazedi Tr. 899. Jeuveau® has been approved for

aesthetic use. RX-3162C (Moatazedi WS) at Q/A 27, 30. A company called Alphaeon Corporation (a company within the same corporate family as Evolus and the former owner of Evolus) owns the rights to introduce the same product for therapeutic use in the United States. *Id.* at Q/A 29; RX-3160C (Marmo WS) at Q/A 63–65.

3. Nabota

Nabota is the brand name for the formulation of DWP-450 that is sold by Daewoong in several countries, including South Korea, Thailand, Philippines, Mexico, and India. RX-3167C (KY Kim WS) at Q/A 16.

E. Technological Background

1. Botulinum Neurotoxin (BTX or BoNT)

BTX products have both therapeutic applications, including the treatment of chronic migraine headaches, cervical dystonia, hyperhidrosis, spasticity, and urinary incontinence, and aesthetic applications, including the temporary improvement to the appearance of glabellar lines (sometimes called frown lines), lateral canthal lines (sometimes called crow's feet), and forehead lines. *See* Joint Technology Stipulation at 2 (July 26, 2019) (EDIS Doc. ID No. 683401). BTX products are made from *C. botulinum*, which produces a highly potent neurotoxin that can cause muscle paralysis and death and must be carefully handled. *Id.* *C. botulinum* is the bacteria that causes botulism. *See* CX-0010C (Pickett WS) at Q/A 66-67. In a typical cosmetic procedure, a 50-unit or 100-unit vial of a BTX product is injected via syringe into the muscle of the target area. CX-0016C (Neervannan WS) at Q/A 11. The BTX product operates as a neuromuscular blocking agent, which functions by temporarily interfering with nerve signals and temporarily relaxing targeted muscles through localized injections. *Id.* at Q/A 9.

All BTX products require use of a commercially viable *C. botulinum* strain. Different strains of *C. botulinum* produce different serotypes of neurotoxin. *See* CX-0010C (Pickett WS) at Q/A 67. The serotypes have been labeled alphabetically from serotype A to serotype G, and there are subtypes within each serotype (*e.g.*, A1, A2, etc.). *Id.* Type A1 BTX products are the most commercially viable. *Id.* at Q/A 68. However, not every Type A1-producing strain can be used to make a commercial product; the properties of the strain are exceptionally important when considering whether it can be used for a commercial product. *Id.* at Q/A 70.

In addition to requiring a strain, producing a BTX product requires a carefully calibrated manufacturing process. The manufacturing process for BTX products includes the manufacturing of the drug substance (also called the API or the "bulk") and the drug product (the finished dosage form sold to consumers). *See* Joint Technology Stipulation at 3 (July 26, 2019). Manufacture of the BTX drug substance involves culturing the *C. botulinum* bacteria, and then separating, isolating, and purifying the neurotoxin complex. *Id*.

When cultured (*i.e.*, grown), the *C. botulinum* bacteria secrete the neurotoxin protein molecule along with several other neurotoxin associated proteins. *See* CX-0010C (Pickett WS) at Q/A 187. These collectively, together with the neurotoxin protein molecule, form the whole protein complex, which is called the neurotoxin complex. *See id.* The molecular weight of this whole neurotoxin complex can vary, but the largest size is 900 kDa. *See id.* The whole neurotoxin complex can be used for a BTX product. *See id.* The neurotoxin complex can also be further purified, if desired, to varying degrees until all the proteins, with the exception of the neurotoxin protein molecule, are removed.

See id. The pure neurotoxin protein molecule can also be used for a BTX product. *See id.* The BTX products of Medytox, Allergan, and Daewoong all use the neurotoxin complex, with a molecular weight of 900kDa. *See id*.

After the drug substance is obtained, it must be formulated and packaged into the final drug product (*i.e.*, a form that can be used by and sold to clinicians). Production of the drug product involves combining the drug substance with additional ingredients known as excipients, which are used to stabilize the neurotoxin molecules and provide a sterile preparation of the product for injection. *See* Joint Technology Stipulation at 4 (July 26, 2019). BTX products can be sold in either a solid or liquid form using a variety of excipients. *See id.* The solid forms can be a powder that is either freeze-dried (or "lyophilized") or vacuum-dried, which must be diluted with a suitable liquid prior to injection. *See id*. The liquid forms do not require this step and can be injected directly. *See id.*

The Hall A-hyper strain, a strain of *C. botulinum*, was developed by U.S. army researchers in the 1940s and has been prized ever since for its characteristics that cannot be found in other *C. botulinum* strains. Researchers at the U.S. Army Medical Research Institute of Infectious Diseases ("USAMRIID") developed the Hall A-hyper strain by screening colonies of the bacteria for high toxin producers over several iterations. *See* JX-0124.3 (Schantz & Johnson (1992)); Keim Tr. 203–205. As an exceptionally productive strain, the Hall A-hyper strain makes the separation and purification process easier and the manufacturing process safer. It is also stable, which means it does not degenerate over time to a strain that produces less neurotoxin. Finally, it only sporulates

poorly and does not form spores[5] during the manufacturing process, which streamlines downstream processing and helps manufacturers meet the high standards required for making botulinum toxin. *See* CX-0010C (Pickett WS) at Q/A 71–83; CX-0013C (Jung WS) at Q/A 37.

2. DNA Sequencing

The genome of any organism is the sum total of the DNA that encodes all of the cellular machinery necessary for the organism to carry out life. *See* CX-0015C (Keim WS) at Q/A 14. DNA is composed of four nucleotides: adenine (A), cytosine (C), guanine (G), and thymine (T). *See id*. at Q/A 60. The sequence arrangement of these four nucleotides provides the information that controls the biological activity of the organism. In *C. botulinum* type A1 bacteria, the genome is roughly 3.5 to 4 million nucleotides in length, depending on the particular strain of the bacteria. The Hall A-hyper strain (from Fort Detrick) has been sequenced to 3,760,560 nucleotides in length. *See* CX-1939; CX-0015C (Keim WS) at Q/A 159–61 (discussing CX-1939 and GenBank submission for CP000727.1). Portions of the genome sequence encode discrete genes (coding regions), which encode a specific protein or enzyme that is used by the cell to carry out a biological function. Other portions of the genome sequence do not encode any genes at all (non-coding regions) and can either serve as a spacer between genes or may serve a functional role that aids in the proper expression of a gene into a protein or enzyme. *See* Keim Tr. 218–219.

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[5] Spores, also called endospores, are employed by some bacteria when they encounter adverse conditions. Certain bacterial cells may convert into dormant spores, which are robust bodies that can withstand extreme conditions. *See* RX-3164C (Wilson WS) at Q/A 179.

Before the early 2010s, scientists employed a sequencing technique first developed by Dr. Frederick Sanger in the early 1970s. RX-3165C (David Sherman WS) at Q/A 15. The Sanger sequencing method can be used to obtain continuous sequences of up to 1,000 nucleotides or more. It is considered the "gold standard" by most scientists in terms of the quality and accuracy of the sequences obtained. *See* CX-0015C (Keim WS) at Q/A 156–58. The Sanger sequencing method is not without drawbacks, however, as it can be a laborious, time-consuming, and expensive process to use for sequencing whole genomes; however, its accuracy is rarely questioned. CX-0015C at Q/A 158. In the case of the Hall A-hyper strain, which has a total length of 3.76 million nucleotides, thousands of reads ("reads" are continuous fragments of DNA) are required to assemble the full-length genome, because each read has a length of roughly 1,000 nucleotides.

In the early 2010s, new technologies such as next generation sequencing (NGS) (developed by companies like Illumina) and single-molecule, real-time (SMRT) sequencing (developed by companies like Pacific Biosciences ("PacBio")) came into use by the scientific community to sequence longer DNA sequences, including whole genome sequences (WGS). *See* RX-3165C (Sherman WS) at Q/A 18–26. The main advantage of the NGS and SMRT technologies is that the cost of sequencing DNA is, on a per-nucleotide basis, less than 1% the cost of sequencing using the Sanger method. It is also less time-consuming to obtain the data, as it is largely reliant on computer algorithms and software to generate the nucleotide sequences and assemble longer, continuous fragments of nucleotide sequences. *Id*.

NGS techniques developed by Illumina shears the DNA desired to be sequenced into fragments that are read by the Illumina machine. *See* CX-0015C (Keim WS) at Q/A

60. Illumina techniques generate "reads" of approximately 250 nucleotides in length. *Id.* at Q/A 62. The accuracy of the nucleotide sequence for each Illumina read is believed to be in the 99 to 99.9% range. *See generally* CX-0015C at Q/A 58–67; RX-3165C at Q/A 18–26. Even with a 99.9% accuracy rate, however, on a 250-nucleotide read, that means on average there are 0.25 errors per read. *Id.* This low accuracy rate is overcome by reading between 50 to 200 different DNA fragments that cover each nucleotide position. *Id.* However, the number of fragments covering each nucleotide position (*i.e.*, the depth of coverage) is not uniform across the entire length of the genome due to the random shearing.[6] *Id.* With enough reads, algorithms can calculate the most likely or "consensus" nucleotide for each given nucleotide position on the DNA sequence. *Id.* Computer algorithms also process the millions of DNA fragments in order to "assemble" the 250 nucleotide fragments into longer assemblies of longer continuous lengths by determining overlaps of sequences. *Id.* Ideally, the fragments can be assembled into a single genomic sequence without any breaks. *See generally* CX-0015C (Keim WS) at Q/A 58–67; RX-3165C (Sherman WS) at Q/A 18–26.

Real-time sequencing developed by PacBio also divides the DNA desired to be sequenced into fragments longer than those used by Illumina NGS technology. RX-3165C (Sherman WS) at Q/A 18–26. PacBio reads are between 10,000 to 15,000 in length, and each fragment is read multiple times. *Id.* The accuracy of the nucleotide sequence for each PacBio read is believed to be in the 85% range. *Id.* This low accuracy rate is overcome by the multiple reads per nucleotide position and having the computer

[6] It is possible that some nucleotide positions have less than 20 fragments covering that particular nucleotide position while other positions have over 250 fragments covering that particular position. *See*, *e.g.*, CX-0015C (Keim WS) at Q/A 66, 90, 194.

algorithm determine the "consensus" nucleotide for each position. *Id*. While PacBio sequencing provides longer continuous DNA sequence fragments, the high error rate limits the usefulness of sequences determined by PacBio technology. *Id*.

3. Laboratory Bacterial Culturing Versus Bacteria in Nature

The most common method of growing up large numbers of bacteria is liquid culturing, in which a small amount of the desired bacteria is suspended in a liquid medium comprised of nutrients that are desired by the bacteria. *See*, *e.g.*, CX-0010C (Pickett WS) at Q/A 118. Scientists may refer to "growing" or "expanding" bacteria as synonyms for bacterial culturing to increase the number of bacteria. This does not refer to making the bacterial cells larger in size, but merely in number. Depending on the density of cells in the liquid medium, the temperature, concentration of oxygen and carbon dioxide, the concentration of nutrients remaining in the liquid medium, the particular strain of bacteria, the presence of any selective factors, whether they are expending their energy producing botulinum toxin, and a variety of other factors, the population of bacteria can double every 20 to 60 minutes.

When a bacterium (or any other living organism) reproduces, the cell must replicate its genomic DNA so that each cell has a copy of genome. For bacteria, the enzyme that replicates the DNA is roughly estimated to have an error rate of about 1 error per 100 million (10^8) to 1 error per 1 billion (10^9) nucleotides that it copies. CX-1939 (Smith TJ, *et al*. (2007)). The genome of the *C. botulinum* strains at issue is roughly 3.7 million nucleotides in length. *Id*.

The mixture of cells having slightly different genomes that can arise by culturing in a laboratory can be maintained by using a method called direct culturing or mass

propagation. *See generally* CX-0015C (Keim WS) at Q/A 120–21; RX-3165C (Sherman WS) at Q/A 119. This is typically done by taking a small volume of the bacterial culture that has been cultured for some period of time.

For example, a single bacterium may be placed into a flask containing 10 mL of culture media. After a day or two, the single bacterium has expanded into hundreds of trillions of cells. One might refer to this 10 mL culture of bacteria as "Culture A." The scientist can take a small aliquot (*e.g.*, 100 µL) of Culture A and inoculate a new tube or flask containing fresh culture media. Even this small aliquot (1% of the total volume of Culture A) will contain trillions of cells. Depending on the random mixture of cells contained in that 100 µL aliquot, the second culture tube or flask (which we refer to as "Culture D") would likely have a similar mix of cells comprising the different genomes as those cells in the first tube. This method of culturing that results in Culture D is referred to as direct culturing or mass cell propagation. *See* CX-0015C (Keim WS) at Q/A 120–21.

Scientists can take advantage of the natural mutation rate to select and isolate single cells and start new cultures that allow the mutants to multiply further without competition. *See generally id.*; RX-3165C (Sherman WS) at Q/A 119. One can take the 10 µL aliquot (or perhaps even less) from Culture A and place them onto a plate that has a gelatin-like media (*e.g.*, agar or egg yolk agar (EYA)) on which the bacteria can grow. By using the "streaking" method, one can isolate a single cell from which an isolated colony that will form over the next couple of days. That single isolated colony can be used to inoculate another tube or flask containing fresh culture media and, after a day or two, we have another culture of bacteria we will refer to as "Culture A1." This method

of culturing that results in Culture A1 is referred to as single colony isolation. *See* RX-3165C (Sherman WS) at Q/A 119. If the single isolated colony from the streak has a mutation in its genome that did not exist in the original bacterium that started Culture A, then Culture A1 is almost certainly not going to contain any bacteria that have a genome identical to the original bacterium that started Culture A, as the rate and occurrence of mutations in the DNA replication process appear random and haphazard. Given the rapid growth of bacteria, this process of repeating the single cell isolation and inoculation in serial fashion (*i.e.*, streaking a isolate a single colony from Culture A1 to inoculate Culture A2, then isolating a single colony from Culture A2 to inoculate Culture A3, etc.) can easily result in creating and isolating a bacterial culture having several mutations from the original bacterium in a matter of weeks. *Id.*

While mutations can be readily isolated and cultured in a laboratory setting in a matter of days, mutations do not arise that quickly in nature. *See generally id.* at Q/A 127. *C. botulinum* are anaerobic bacteria and, as such, must be cultured under conditions having minimal or no oxygen. If the concentration of oxygen exceeds a certain low threshold or other unfavorable conditions exist (*e.g.*, insufficient nutrients remaining in the liquid media, overcrowding of bacteria, etc.), the bacteria will either die off or sporulate (*i.e.*, form endospores). *See* RX-3164C (Wilson WS) at Q/A 179. It takes several hours for a bacterium to form an endospore, so sudden changes to the environment to make it hostile for the bacterium will result in death rather than survival in spore form. *C. botulinum* spores can survive extreme conditions for some time, depending on the severity of the conditions. *C. botulinum* spores are known to survive temperatures below -200°C, or even bursts of radiation. *Id.*

Growing bacteria in culture media under favorable conditions for their exponential expansion and/or cultivation for toxin production is a highly artificial condition that simply does not exist in the natural world. In nature, if the *C. botulinum* is not inside a host organism or an inaccessible, anaerobic environment that somehow has abundant nutrients for the *C. botulinum* to flourish and to multiply, the bacteria will exist as spores. On the soil surface, for example, the bacteria are exposed to high levels of oxygen (*i.e.*, the normal concentration of oxygen in the atmosphere at sea level is about 21%). They would also face an environment lacking nutrients, extreme temperatures, etc. Thus, *C. botulinum* bacteria that exist in nature are mostly going to exist as spores, unless they are deep in the soil or under other conditions where they are not exposed to oxygen, such as inside another living organism or carcass. Thus, new mutations in *C. botulinum* may take years, even thousands of years, to occur, if in the meantime conditions are never ripe for the *C. botulinum* to attempt to multiply. Sherman Tr. 833–834 (in the environment, the bacteria exist in a spore state until some point in time "when nutrients become available"). Yet, it is also possible the *C. botulinum* is exposed once every few months to anaerobic conditions favorable with nutrients (*e.g.*, when ingested by an animal host, wind sweeps the spore into a favorable location, rain temporarily causes a deluge that places the spore in an anaerobic, favorable environment, *etc*.) and mutations have the opportunity to arise as DNA replication occurs when the bacteria replicate. *Id*. Given the many variabilities of conditions in nature, it is impossible to estimate the amount of time it takes for mutations to arise in nature. *See* Keim Tr. 173–174.

F. Asserted Trade Secrets

Complainants allege that Daewoong misappropriated (i) Medytox's *Clostridium botulinum* bacterial strain used to manufacture its BTX products, and (ii) Medytox's manufacturing process for Meditoxin. *See*, *e.g.*, Complaint, ¶ 52; Compls. Br. at 37–43, 132–34.

1. Medytox's *C. botulinum* Hall A-hyper Strain

Medytox uses a strain of *C. botulinum* that originated from a subculture of the Hall A-hyper strain. Medytox's *C. botulinum* strain ("Medytox BTX strain" or "Medytox strain") is used to produce botulinum type A drug substance that is formulated into pharmaceutical products that are commercialized as, *inter alia*, Meditoxin and Innotox. *See* CX-0013C (Jung WS) at Q/A 17–19. The botulinum type A drug substance from the Medytox strain is also used in the formulation for MT10109L, a liquid BTX product that Medytox licensed to Allergan for commercialization in the United States. *See id.* at Q/A 20. Medytox alleges that the Medytox BTX strain was misappropriated by Daewoong for the latter's use in the manufacturing of the accused products.

While the Medytox strain is known to be a Hall A-hyper strain, it is genetically distinct from other "Hall A-hyper" strains, including the one that was first reported in 1943 by Drs. Elizabeth McCoy and William Sarles of the University of Wisconsin – Madison as a strain that produced more toxin per unit of culture than any other strain they tested. *See* CX-0005.3 (Smith TJ declaration). The high level of toxin production by the Hall A-hyper strain and strains derived from subcultures of the original Hall A-hyper strain is one characteristic that makes these strains unique and commercially valuable, as compared to the thousands of "Hall" strains and other non-Hall strains of *C. botulinum*.

Another characteristic associated with the Hall A-hyper strains is that they sporulate poorly, if at all. *See* CX-0010C (Pickett WS) at Q/A 71–72. This is a desirable quality for commercial processes, especially in pharmaceutical BTX manufacturing, as contamination of manufacturing equipment and/or the drug product with spores require additional processing to eliminate the spores. *See id.*

Complainants allege that Daewoong misappropriated Medytox's strain of *C. botulinum*, and uses it to produce DWP-450. It is further alleged that Daewoong obtained Medytox's strain through former Medytox employee Dr. Byung Kook Lee (also referred to as "BK Lee"). *See*, *e.g.*, Compls. Br. at 37. Respondents deny misappropriating the strain, as does Dr. BK Lee. *See*, *e.g.*, Resps. Br. at 161–63.

2. Medytox's Manufacturing Processes for 900 kDa botulinum toxin

Medytox also alleges that Daewoong misappropriated Medytox's secret manufacturing processes and related testing information for its 900 kDa botulinum toxin products, including Meditoxin, Innotox, and MT10109L. For example, there are allegations that former Medytox employee BK Lee took without authorization at least the following documents that memorialize some or all of the manufacturing processes, and related testing information:

- Batch record for Meditoxin: It is alleged that BK Lee printed 17 critical pages from the batch record detailing the step-by-step manufacturing process (including directions for [

  ] for the drug substance. *See* CX-0011C (Rhee WS) at Q/A 47; CX-0017C (Chang WS) at Q/A 167; CX-2068C (SecuPrint image of Batch Record version no. 05, version date Sept. 11, 2006). These pages contain the specifications for the equipment and ingredients used in the GMP-approved manufacturing process and allegedly

reflect years of Medytox's research and development work. *See* CX-0011C (Rhee WS) at Q/A 46–49.

- Experimental batch record: It is alleged that BK Lee emailed to his personal account an 18-page experimental batch record reflecting an experimental manufacturing process and certain innovations being studied by Medytox, including [ ]. *See* CX-0017C (Chang WS) at Q/A 173; CX-0011C (Rhee WS) at Q/A 50, 56–59; CX-2063C (attachment to email titled Experimental Batch Record Version No. 04).

- Characterization report and related test results and methods: It is alleged that BK Lee printed portions of two different characterization reports, along with various underlying biochemical analysis reports. *See* CX-0017C (Chang WS) at Q/A 165; CX-0011C (Rhee WS) at Q/A 63–91; CX-2067C (SecuPrint image of Characterization Report of Botulinum Toxin Type A); CX-2069C – CX-2084C (SecuPrint images of various analyses of the drug substance). A characterization report records the physiochemical properties, structural characterization and conformation, biological activities, immunological properties, and purity, as well as the specific tests performed to determine the characteristics of a drug substance. *See* CX-0011C (Rhee WS) at Q/A 60.

- Project and quality plan and attachments: It is alleged that BK Lee emailed to his personal account Medytox's project and quality plan, and certain attachments to the same. *See* CX-0017C (Chang WS) at Q/A 170–72, 175–76; CX-2064C (attachment to email titled Project and Quality Plan for Botulinum Toxin Type A Complex Facility); CX-2059C – CX-2062C (attachments to email containing CX-2064C); CX-0436C, CX-0437C – CX-0444C (additional attachments to Project and Quality Plan). These documents detail building a manufacturing facility and manufacturing a drug substance in compliance with GMP standards. *See* CX-0011C (Rhee WS) at Q/A 92–101.

- Meditoxin common technical document: It is alleged that BK Lee emailed to his personal email account portions of Medytox's common technical document, which describes the approved manufacturing process for Meditoxin and contains much of the same information reflected in the other documents listed above. *See* CX-1526C (Sep. 7, 2007 email to/from BK Lee), CX-1527C (portion of common technical document attached to CX-1526C).

See, *e.g.*, Staff Br. at 20–22; Compls. Br. at 176–80; Compls. Reply Br. at 2.

Respondents argue, and Dr. BK Lee testified, that his emails and printings were authorized or in line with the practices in place at Medytox when he was there. Resps. Br. at 187–94.

II. Jurisdiction

A. *In Rem* Jurisdiction

Evolus does not contest *in rem* jurisdiction as to Jeuveau®, as it does not contest that it imports and sells Jeuveau® after importation. Respondents argue that complainants have not shown that there is *in rem* jurisdiction as to Nabota® or DWP-450, because respondents do not import or sell them after importation into the United States. However, respondents admit that both Nabota® and DWP-450 have previously been imported into the United States. Due to the importation of Jeuveau®, Nabota, and DWP-450, the Commission has *in rem* jurisdiction over the accused products. *See*, *e.g.*, *Sealed Air Corp. v. Int'l Trade Comm'n*, 645 F.2d 976, 985–86 (C.C.P.A. 1981) (noting that the Commission has jurisdiction over imported goods).

B. Personal Jurisdiction

No party has contested the Commission's personal jurisdiction over it. Moreover, both Daewoong and Evolus have appeared and participated in this investigation. It is therefore found that the Commission has personal jurisdiction over all parties.

C. Subject Matter Jurisdiction

Complainants argue that section 337 provides that the Commission shall investigate alleged unfair acts, such as those alleged in the complaint. *See* 19 U.S.C. § 1337(a)(1)(A). In complainants' view, section 337 serves a broad "protective function, in that it protects the domestic market from those products sold in the United States, which are the fruits of unfair competition." Compls. Reply at 29; *Certain Welded Stainless Steel Pipe and Tube*, Inv. No. 337-TA-29, Comm'n Op. at 12, 1978 WL 50692, at *8 (Feb. 22, 1978).

Respondents argue, in part:

> The ITC . . . does not have jurisdiction over wholly foreign disputes. Section 337 does not extend the ITC's jurisdiction extraterritorially to reach alleged infringement of purely foreign intellectual property rights based on entirely foreign activity. Much like how the ITC's jurisdiction does not reach infringement of a foreign patent even if the resulting product made by such infringement is imported into the U.S., the ITC's jurisdiction does not reach alleged misappropriation of a Korean company's Korean trade secrets based on activity solely in Korea by another Korean company.

In general, U.S. law does not provide a cause of action to foreign parties for misconduct that allegedly occurred in foreign jurisdictions — there is a presumption against extraterritoriality when interpreting U.S. statutes. *See Kiobel v. Royal*, 569 U.S. 108 (2013); *Morrison v. National Australia Bank Ltd*., 561 U.S. 247 (2010). Thus, "[w]hen a statute gives no clear indication of an extraterritorial application, it has none." *Morrison*, 561 U.S. at 255. Moreover, even when a statute provides for some extraterritorial application, "the presumption against extraterritoriality operates to limit that provision to its terms." *Id.* at 265.

There is no statutory language that expresses clear intent for Section 337 to apply to extraterritorial intellectual property rights. For example, the statutory provisions of Section 337 are limited to infringement of U.S. patents, U.S. trademarks, U.S. mask works, and U.S. designs. There is no express language extending the provisions of Section 337 to infringement of foreign patents, foreign trademarks, foreign mask works, and foreign designs. Similarly, there is no statutory language that supports that the unfair acts under Section 337 can be based on misappropriation of foreign intellectual property.

The legislative history also does not support extraterritoriality. Rather, the original purpose of Section 337 was to protect U.S. manufacturers and U.S. intellectual property rights. *See* Kinter 1978 Legislative History of Antitrust Laws at 6014, 6127. During the Senate debate for the Tariff Act of 1930, senators explained that Section 337 was "drafted in response to the appeals and demands of American manufacturers. . ." *Id*. The passage of the 1988 amendment to Section 337 further emphasized that the

purpose of the statute is to protect U.S. intellectual property rights against imports that cause financial losses to American companies.

Moreover, the Federal Circuit has held that the extraterritorial reach of Section 337 is limited to foreign conduct that relates to importation. "[T]he Commission's investigations, findings, and remedies affect foreign conduct only insofar as that conduct relates to the importation of articles into the United States." *TianRui Group Co. Ltd. v. Int'l Trade Comm'n,* 661 F.3d 1322, 1322 (Fed. Cir. 2011). Although the dissent in *TianRui* read Section 337 to preclude entirely acts of misappropriation that occurred outside of the U.S., *id.* at 1338-42, the majority interpreted Section 337 to include misappropriation of U.S.-developed and U.S.-owned trade secrets in China where the asserted U.S. trade secrets were licensed by the U.S. manufacturer and thus were of value to the U.S. manufacturer. The Federal Circuit has never interpreted Section 337 to extend to foreign intellectual property rights.

Complainants seemingly allege that Section 337 has extraterritorial reach because it governs "unfair methods of competition and unfair acts in the importation of articles" that are manufactured outside of the United States. CPB at 23-24. That is inapposite. The "unfair methods of competition and unfair acts" under Section 337 are limited to violations of domestic rights. Indeed, the parties and Staff agree that Complainants' claims are governed by U.S. trade secret law. CPB at 24-25 (stating that the Commission applies "a single federal standard," and citing the Restatement of the Law of Torts § 757, 18 U.S.C. § 1839(3), and the Uniform Trade Secrets Act § 1(4)); SPB at 28 (same).

Here, however, there are no U.S. trade secrets at issue. Rather, the undisputed facts make clear that the asserted trade secrets were allegedly created in Korea by a Korean company (with no U.S. subsidiaries), used solely in Korea, and kept exclusively in Korea. This stands in stark contrast to *TianRui*, in which the trade secrets had been developed and practiced in the United States by their owner, a U.S. company, which was the complainant. *TianRui*, 661 F.3d at 1324. Here, the asserted trade secrets are so closely tied to Korea that they are considered Korean national core technology under Korean law and a civil lawsuit between the

> parties involving identical allegations has been pending in Korea for the last two years. Both California and Indiana state courts have also independently concluded that Medytox's misappropriation allegations against Daewoong should be adjudicated in Korea. *See supra* II.A.
>
> Moreover, the evidence makes clear that no U.S. company has rights to the foreign-developed and foreign-owned alleged trade secrets. Complainant Medytox, the alleged developer and owner of the asserted trade secrets, is indisputably a Korean company with no U.S. presence. And co-Complainant Allergan indisputably did not develop the alleged trade secrets and does not own, license, have access to, possess them, or use them, as explained in much greater detail below at III.D.2.b.i.
>
> The asserted trade secrets at issue here are purely Korean trade secrets — there are no U.S. trade secret rights at issue in this case. Given the facts of this case and the extraterritorial nature of the dispute, the ITC does not have subject matter jurisdiction over Complainants' allegations regarding the misappropriation of the alleged Korean trade secrets.

Resps. Br. at 47–50 (footnotes omitted).[7]

Complainants argue that the Commission has subject matter jurisdiction over this investigation because the complainants allege that respondents have committed an unfair act, and section 337 provides that the Commission shall investigate such alleged unfair acts. *See* Compls. Br. at 28. Complainants argue it is irrelevant whether the asserted trade secrets are U.S.-based intellectual property rights or not because subsection (a)(1)(A) of section 337 is not so limited, but rather protects U.S. industry against any "[u]nfair methods of competition and unfair acts in the importation of articles . . . into the United States." *Id.* The complainants cite *TianRui Grp. Co. Ltd. v. Int'l Trade Comm'n*, 661 F.3d 1322, 1332 (Fed. Cir. 2011), *see id.*, as explaining that any concerns about the

[7] Emphasis in original unless noted otherwise.

extraterritorial application of subsection (a)(1)(A) are balanced by the fact that "[t]he Commission's investigations, findings, and remedies affect foreign conduct only insofar as that conduct relates to the importation of articles into the United States."

The Staff agrees with the complainants, arguing that the Commission has subject matter jurisdiction because Medytox and Allergan properly filed a complaint alleging a violation of 19 U.S.C. § 337(a)(1)(A). *See* Staff Br. at 26–27.

The Commission has subject matter jurisdiction in this investigation because complainants filed a complaint alleging a violation of section 337. Furthermore, the administrative law judge finds that respondents' extraterritoriality argument was rejected by the Federal Circuit in *TianRui*, which held that section 337 "does not purport to regulate purely foreign conduct" because "of the statute's focus on the act of importation and the resulting domestic injury." 661 F.3d at 1329. The determination in *TianRui* did not turn on whether the trade secrets at issue had been developed and practiced in the United States.[8] The salient point was that the imported goods at issue were imported and injured, or could injure, a domestic industry.

Contrary to respondents' interpretation of the *TianRui* decision, the majority opinion imposed no limitations regarding U.S. development and U.S. ownership of the trade secrets in the majority opinion:

> [E]ven if we were to conclude that section 337 is ambiguous with respect to its application to trade secret misappropriation occurring abroad, we would uphold the Commission's interpretation of the scope of the statute. As it is, we conclude that the Commission's longstanding

[8] The *TianRui* decision did not look to the laws of the state in which the intellectual property was alleged to have been created. Rather, the Federal Circuit looked to a single federal standard to determine whether there was trade secret misappropriation under section 337. *TianRui*, 661 F.3d at 1327.

> interpretation is consistent with the purpose and the legislative background of the statute, and we therefore hold that it was proper for the Commission to find a section 337 violation based in part on acts of trade secret misappropriation occurring overseas.

TianRui, 661 F.3d at 1332. Relevant to the Commission's subject matter jurisdiction is the following:

> [T]he foreign 'unfair' activity at issue in this case is relevant only to the extent that it results in the importation of goods into this country causing domestic injury. In light of the statute's [*i.e.*, Section 337] focus on the act of importation and the resulting domestic injury, the Commission's order does not purport to regulate purely foreign conduct. Because foreign conduct is used only to establish an element of a claim alleging a domestic injury and seeking a wholly domestic remedy, the presumption against extraterritorial application does not apply.

Id. at 1329 (internal citation omitted). Section 337 sets conditions under which products may be imported into the United States. *Id*. at 1330.

Subsection (a)(1)(A) of section 337 protects U.S. industry against any "[u]nfair methods of competition and unfair acts in the importation of articles . . . into the United States." As the Federal Circuit explained in *TianRui*, concerns about the extraterritorial application of subsection (a)(1)(A) are obviated by the fact that "[t]he Commission's investigations, findings, and remedies affect foreign conduct only insofar as that conduct relates to the importation of articles into the United States." 661 F.3d at 1332.

Inasmuch as the statutory language requires that a complainant demonstrate that the imported articles at issue have the threat or effect of destroying or substantially injuring an industry in the United States, respondents' concerns regarding extraterritoriality are not persuasive. The administrative law judge finds that the Commission has subject matter jurisdiction based on the alleged (and in this case proven)

importation of products made by misappropriated trade secrets, which has resulted in harm to the domestic industry. *See Certain Rubber Resins and Processes for Manufacturing Same*, Inv. No. 337-TA-849, Initial Determination, at 16–18 (June 17, 2013) (unreviewed in relevant part) (Comm'n Op. (EDIS Doc. ID No. 525763) (Jan. 15, 2014)).

III. Standing

A. Medytox Standing

Respondents argue, in part:

> [B]y its own recitation of the facts Medytox came into possession of its copy of the Hall A strain through a series of free transfers among researchers. It has therefore failed to establish that it owns or exclusively licenses the strain, to the extent the strain can be considered a trade secret at all (which it cannot). Medytox's asserted process-based information also mirrors the public literature sources Medytox concedes it relied upon in developing its process, meaning that Medytox does not own or exclusively license any process-based trade secrets either. For these reasons, Medytox does not have standing to bring a claim of trade secret misappropriation here. *See, e.g.*, *Rubber Resins,* ID, at 47.

Resps. Br. at 53.

In their prehearing brief, respondents stated: "In this case, it is Medytox, if anyone, that has a colorable basis to assert standing, as it claims to be the exclusive owner of the asserted trade secrets." Resps. Prehearing Br. at 46. Respondents included a footnote with a vague statement that "[i]t is unclear whether even Medytox can establish standing, given evidence that it does not own the asserted trade secrets, among other issues." The administrative law judge finds this insufficient under Ground Rule 7c (pertaining to prehearing briefs), which states that "[a]ny contentions not set forth in

detail as required therein shall be deemed abandoned or withdrawn[.]" Order No. 26 (Oct. 24, 2019).

Furthermore, as discussed herein (Sections VI and VII), Medytox has established ownership of its trade secret strain and manufacturing process.

B. Allergan Standing

Complainants first argue that Commission precedent requires only one complainant to demonstrate standing. *See* Compls. Br. at 29–31. Complainants cite Commission Rule 210.12, which states that, for intellectual-property-based investigations, the complaint must "include a showing that at least one complainant is the owner or exclusive licensee of the subject intellectual property." 19 C.F.R. § 210.12(a)(7). Complainants cite *Certain Diltiazem Hydrochloride and Diltiazem Preparations* ("*Diltiazem Preparations*"), Inv. No. 337-TA-349, Order No. 35, 1994 WL 930265 (Sept. 2, 1994), where a party that purchased a patented compound from the patent owner and manufactured and sold products produced therefrom had "sufficient commercial and legal interest to appear as a joint complainant with . . . the patent owner." *Diltiazem Preparations*, Order No. 35 at *2. Complainants contend the same principle applies for Allergan.

Complainants thus argue that the demonstration of the ownership by Medytox, combined with the additional showing that Allergan has suffered a concrete "injury in fact" (*i.e.*, injury to the domestic industry for BTX products) evidences that both parties have direct interests at stake in the investigation's outcome: the owner of the asserted trade secrets (Medytox) and the domestic industry participant most likely to be directly injured by respondents' unfair acts (Allergan). *See* Compls. Br. at 29–31; *Lujan v.*

Defenders of Wildlife, 504 U.S. 555, 560 (1992); *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547-48 (2016) ("The plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.").

Respondents argue, in part:

> "[T]he same standing requirements apply before the [International Trade] Commission and before Article III courts." *Certain Wireless Devices, Including Mobile Phones & Tablets II*, Inv. No. 337-TA-905, Order No. 12 at 7 (May 1, 2014) ("*Certain Wireless Devices"*). In both, the question of standing is jurisdictional, and it is the complainant's burden to prove that it has cleared this critical threshold. *See, e.g.*, *SiRF Technology, Inc. v. International Trade Commission*, 601 F.3d 1319, 1327-28 (Fed. Cir. 2010); *Certain Semiconductor Chips with Minimized Chip Package Size and Products Containing Same*, Inv. No. 337-TA-605, ID at 14 (December 1, 2008) (*unreviewed in relevant part*). The standing requirement dictates that "the plaintiff generally must assert his own legal rights and interests, and cannot rest his claim to relief on the legal rights or interests of third parties." *Warth v. Seldin*, 422 U.S. 490, 499 (1975). At the ITC, "[t]he unique nature of section 337 gives rise to a host of additional practical reasons . . . as to why the standing rule should be read into Commission practice at least as strictly as elsewhere," including the need for certainty as to which entities can assert private intellectual property rights, and which entities can be bound by any consequences of those assertions. *Certain Catalyst Components and Catalysts for the Polymerization of Olefins*, Inv. No. 337-TA-307, Order No. 12, 1990 WL 710699, at *5-7 (Mar. 22, 1990) ("*Catalyst Components*").
>
> In a trade secret case at the ITC, it is the party that owns or exclusively licenses the alleged trade secrets that has standing to assert their misappropriation. *See, e.g.*, *Rubber Resins*, ID, at 44 (*aff'd in relevant part*) (in order to have standing to assert a trade secret misappropriation claim at the Commission, "the Commission Rules require the complainant [to] own the trade secrets at issue or be the exclusive licensee"); *Certain Cast Steel Ry. Wheels, Certain Processes for Mfg. or Relating to Same & Certain Products*

> *Containing Same*, Inv. No. 337-TA-655, ID, at 17 (Oct. 16, 2009) ("*Cast Steel Wheels*") (complainant "has established that it owns the trade secrets asserted in this investigation, and that it has standing"); *Activity Tracking Devices*, Order No. 55, at 4 (Apr. 27, 2016) (complainants had standing where "there is no dispute that Complainants have possession and *title* to the asserted trade secrets") (emphasis added). In the above and all other Section 337 trade secret investigations of which Respondents are aware, the party found to have standing by virtue of its legal interest in the trade secrets *also* alleged its own domestic industry. In other words, the legal strategy adopted here by Complainants — where one party claims to hold legal interest in foreign trade secrets, and another unrelated entity claims to have the domestic industry/injury, with neither having both — appears to be completely unprecedented.

Resps. Br. at 54–55.

Complainants also argue that Allergan demonstrated that it has standing because it is the exclusive licensee of MT10109L in the United States, and Allergan is therefore entitled to both the benefit of the intellectual property that inheres in the license for which it paid valuable consideration, and to seek redress against respondents' unfair competition in misappropriating those same intellectual property rights. *See* Compls. Br. at 31–34.

In 2013, Allergan and Medytox entered into a license agreement granting Allergan an exclusive worldwide license (excluding only Korea and Japan) [

]. *See* Compls. Br. at 32; JX-0050C.20 (License Agreement); Neervannan Tr. 445–448. The license includes "[

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].” JX-0050C.20.[9]

Complainants argue that MT10109L is manufactured using the same BTX strain that complainants allege Daewoong misappropriated and that is the subject of this Investigation. *See* Compls. Br. at 32; CX-0011C (Rhee WS) at Q/A 7, 10; CX-0013C (Jung WS) at Q/A 19–20.

Additionally, complainants argue that Allergan’s exclusive license to MT10109L [ ]. *See* Compls. Br. at 32–33. Complainants contend the evidence established that the manufacturing trade secrets at issue and the R&D work that generated those trade secrets served as the foundation for the development of the manufacturing process for MT10109L. *See id.* at 33; CX-0017C (Chang WS) at Q/A 70; CX-0012C (HW Kim WS) at Q/A 90; CX-0013C (Jung WS) at Q/A 68; CX-0011C (Rhee WS) at Q/A 54–55. Complainants argue that Allergan has more than a “sufficient commercial and legal interest to appear as a joint complainant” with respect to that intellectual property, because it is the exclusive licensee for MT10109L. *See* Compls. Br. at 33 (quoting *Diltiazem Preparations*, Order No. 35 at *2).

Complainants argue that the Commission has expressly sanctioned standing in similar circumstances. *See* Compls. Reply Br. at 33–34. In *Diltiazem Preparations*, Tanabe, a Japanese corporation, owned the asserted patent but did not engage in any operations in the United States. *Diltiazem Preparations*, ID at 6 (Feb. 1, 1995). The other complainant (MMD) was a U.S. company that was “not licensed . . . to practice the

[9] The agreement defines “[ ]” to include, among other things, “[ ].” *Id.* at JX-0050C.14.

[asserted] patent in the United States." *Id.* at 321. Instead, MMD had a supply agreement with Tanabe under which it purchased bulk diltiazem (which Tanabe manufactured in Japan) that it would further process into pharmaceuticals to sell in the United States. *Id.* at 134, 321. It is argued that during the investigation, respondents challenged whether Tanabe and MMD had a "community of interest" with respect to allegedly privileged documents, and the judge held:

> The Commission has not precluded those who have no legally recognizable rights in the patent from appearing as a coparty complainant. MMD as a purchaser of Tanabe produced diltiazem, and a manufacturer and seller of pharmaceutical products produced from such diltiazem has sufficient commercial and legal interest to appear as a joint complainant with Tanabe, the patent owner.

Diltiazem Preparations, Order No. 35 at *2. It is argued that the same principle applies here for Allergan. *See* Compls. Reply Br. at 33–34.

Respondents argue, in part:

> The basic contours of the 2013 Agreement are simple. Medytox is to manufacture MT10109L, exclusively in Korea. If the product is ultimately approved for sale in the United States, Allergan will market and distribute it in the U.S. (and elsewhere). Allergan also has a role in clinical trials and seeking FDA approval for the product. CX-0011C.49 (Chang Hoon RHEE WS) at Q/A 117; Hearing Tr. 445:23-446:12.
>
> The 2013 Agreement grants Allergan an exclusive license to [
>
>]. JX-0050C.20 (§ 2.1). This exclusive license is exclusive "[ ]." *Id.* [
>
>]. *Id.* at 14-15, 20 (§§ 1.51, 1.60, and 2.1). In other words, [

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].

Allergan is granted exclusive rights to MT10109L [ ]. JX-0050C.20 (§ 2.1). [

]. *Id.* at 15 (§§ 1.56, 1.59). The 2013 Agreement memorializes Allergan's agreement that [

]. *Id.* at 21 (§ 2.3(b)).

Allergan itself has never claimed [ ]. Such a reading of the 2013 Agreement is inconsistent with the performance of the parties under the Agreement. Since the grant of an exclusive license to Allergan is exclusive "[ ]," an interpretation that [

]. CX-0013C.42 (Hyun Ho JUNG WS) at Q/A 18. That simply is not the case. At the evidentiary hearing, Allergan Senior Vice President of Pharmaceutical Development Dr. Sesha Neervannan, the sole witness on the Agreement, confirmed that the grant of rights to Allergan [

].

Hearing Tr. 448:4-8. An interpretation that Allergan has an exclusive license [ ] is also impossible to square with the fact that the 2013 Agreement [

].

> As further proof that Medytox never intended to grant these kinds of rights to Allergan, one need look no further than Medytox's reaction when Allergan publicly announced, to Medytox's apparent surprise, that Allergan would be [
>
>] to begin with. As Allergan's Dr. Neervannan confirmed at the evidentiary hearing, [
>
>].
>
> Hearing Tr. 452:19-23.
>
> The same logic holds with respect to the claimed process-based trade secrets, all of which relate to Medytox's product Meditoxin®. If Staff were correct that Allergan has an exclusive license [
>
>]. That interpretation of the 2013 Agreement makes no sense — it is contrary to [
>
>] and is inconsistent with performance of the parties under the Agreement.

Resps. Br. at 59–61 (footnotes omitted).

The Staff argues that Allergan has standing as a complainant in this investigation because the terms of the September 2013 Medytox-Allergan License Agreement make

clear that Allergan is the exclusive licensee to the asserted trade secrets. *See* Staff Br. at 28–29 (citing JX-0050C).

The terms of the September 2013 Medytox-Allergan License Agreement grant to Allergan "[

].” JX-0050C.020. The product licensed to Allergan is MT10109L, which is manufactured with the Medytox BTX strain—*i.e.*, one of the asserted trade secrets. This is clear evidence that Allergan is the exclusive licensee (outside of Korea) [

] (which includes the asserted trade secrets). The plain language of the license agreement states that Allergan is the exclusive licensee [

], which includes the asserted trade secrets in this investigation. JX-0050C.015. These facts support Allergan's standing.

Indeed, Allergan has an exclusive license as to MT10109L and [

]. JX-0050C.14 (Allergan-Medytox License Agreement). Inasmuch as Medytox is not currently selling any [ ], Allergan is therefore the exclusive licensee of the trade secrets in the United States.

Moreover, significant aspects of the asserted trade secrets are incorporated in the manufacturing of MT10109L, and it uses the misappropriated BTX strain. Allergan is the exclusive licensee of these trade secrets in the U.S. with regard to MT10109L, and therefore has independent standing. *See* CX-0011C (Rhee WS) at Q/A 52, 55, 57, 120;

CX-0012C (Kim WS) at Q/A 90; CX-0017C (Chang WS) at Q/A 70; 19 C.F.R. § 210.12(a)(7); *Certain Static Random Access Memories*, Inv. No 337-TA-341, Order No. 5, 1992 WL 811807, at *2 (Dec. 30, 1992) ("The owner of a patent is not the only possible complainant. A licensed domestic producer of an article that is protected by a U.S. patent may be the complainant."); *Faiveley Transp. USA, Inc. v. Wabtec Corp.*, 758 F. Supp. 2d 211, 220–21 (S.D.N.Y. 2010) (party with "the exclusive rights to manufacture, use, assemble, sell, and market the Products" has "a sufficient interest to confer their holder with standing").

Allergan's exclusive license for MT10109L expressly includes the rights to the asserted trade secrets that are used to make MT10109L. Furthermore, [

]. *See, e.g.*, JX-0050C.30 (License Agreement) [

]; *id.* at JX-0050C.26 (4.2 – Development Responsibilities); CX-2230C.1 (Allergan IND submission).

The administrative law judge finds that Allergan has standing based on its license to sell imported products, which are produced using the allegedly misappropriated trade

secrets, and its claimed injury from the imported accused products to its domestic industry.

At issue for the purposes of the standing question are imported products produced using the allegedly misappropriated trade secrets, not the know-how or the strain in and of themselves. Thus, Allergan is in a position similar to many manufacturers that purchase underlying parts, such as semiconductors, which are produced using trade secrets unknown to the manufacturers. Allergan is a licensee to the underlying trade secrets, [

].

IV. Legal Standards

A. Trade Secrets

The Restatement of the Law of Torts defines a trade secret as:

> [A]ny formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, a treating or preserving materials, a pattern for a machine or other device, or a list of customers. It differs from other secret information in a business … in that it is not simply information as to single or ephemeral events in the conduct of the business … A trade secret is a process or device for continuous use in the operation of the business … .

RESTATEMENT OF LAW OF TORTS § 757, Comment b. Similarly, the Uniform Trade Secret Act ("U.T.S.A.") defines a Trade Secret as "information, including a formula, pattern, compilation, program, device, method, technique, or process, that: (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain,

economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy." *TianRui Group*, 661 F.3d at 1327–28, citing U.T.S.A., § 1(4) (as amended, 1985).

The Commission has identified six relevant factors to assist in determining whether or not a trade secret exists:

(1) the extent to which the information is known outside of complainant's business;

(2) the extent to which it is known by employees and others involved in complainant's business;

(3) the extent of measures taken by complainant to guard the secrecy of the information;

(4) the value of the information to complainant and to his competitors;

(5) the amount of effort or money expended by complainant in developing the information;

(6) the ease or difficulty with which the information could be properly acquired or duplicated by others.

Certain Processes for the Manufacture of Skinless Sausage Casings and Resulting Prods., Inv. No. 337-TA-148/169 ("*Sausage Casings*"), USITC Publ. No. 1624 (Dec. 1984), ID at 245 (July 31, 1984) (*citing* RESTATEMENT OF LAW OF TORTS § 757, Comment b (1939) and MILGRIM, TRADE SECRETS, § 2.01 (1980)). These factors are not a six-part test which must be met to find a trade secret. Rather, they are "instructive guidelines for ascertaining whether a trade secret exists." *See*, *e.g.*, *Learning Curve Toys, Inc. v. PlayWood Toys, Inc.*, 342 F.3d 714, 722 (7th Cir. 2003); *Certain Cast Steel Railway Wheels, Certain Process for Mfg. or Relating to Same and Certain Prods. Containing Same*, Inv. No. 337-TA-655 ("*Railway Wheels*"), Unreviewed ID at 20 (Oct. 16, 2009) (EDIS Doc. ID No. 414899), *see* Notice of Commission Determination Not to Review a Final Initial Determination Finding a Violation of Section 337; Request for

Written Submissions Regarding Remedy, Bonding, and the Public Interest (EDIS Doc. ID No. 416143) (Dec. 17, 2009).

"Matters of general knowledge in the industry, or those that can be readily discerned are not eligible for trade secret protection." *Sausage Casings*, ID (July 31, 1984) (*citing Motorola, Inc. v. Fairchild Camera & Instrument Corp.*, 177 U.S.P.Q. 614, 620–21 (D. Ariz. 1973)). Information that may be eligible for protection as a trade secret may lose that protection if adequate steps are not taken to maintain secrecy. *Sausage Casings*, ID at 246. The burden on complainant is to establish that reasonable precautions were taken to preserve secrecy to ensure that it would be difficult for others to discover the secret without the use of improper means. *Id*. (*citing Henry Hope X-Ray Prods., Inc. v. Marron Carrel, Inc.*, 216 U.S.P.Q. 762, 764, 674 F.2d 1336, 1341 (9th Cir. 1982)). Once a *prima facie* showing is made concerning appropriate safeguarding of trade secrets, the burden shifts to the accused to prove that a trade secret is generally known or readily ascertainable. *Surgidev Corp. v. Eye Tech., Inc.*, 648 F. Supp. 661, 688 n.9 (D. Minn. 1986). Similarly, the respondent bears "a heavy burden" in proving independent development. *Sausage Casings*, ID at 247; *Bolt Assocs., Inc. v. Alpine Geophysical Assocs., Inc.*, 365 F.2d 742, 749–50 (3d Cir. 1966) ("Such a burden cannot rest on mere self-serving assertions, but rather, a heavy burden of persuasion rests upon one so charged to show that the production was the result of independent development and not from the use of information confidentially reposed."); *Pioneer Hi-Bred Int'l v. Holden Found. Seeds, Inc.*, 35 F.3d 1226, 1241 (8th Cir. 1994) ("once [plaintiff] produced convincing evidence of misappropriation, [defendant] was obligated to provide persuasive evidence of lawful derivation"). "Matters disclosed in patents also will destroy

any claims of trade secret." *Sausage Casings*, ID at 246 (citing *Henry Hope X-Ray*, 674 F.2d at 1342). Nevertheless, a party may still be liable for trade secret misappropriation if it used trade secret information prior to its disclosure. *See On-Line Techs., Inc. v. Bodenseewerk Perkin-Elmer GmbH*, 386 F.3d 1133, 1141 (Fed. Cir. 2004) (no liability for using trade secret after its publication).

A specific embodiment of general concepts or a combination of elements, some or all of which may be known in the industry, may be protectable as a trade secret. *Id*. (*citing Cybertex Computer Prods., Inc. v. Whitfield*, 203 U.S.P.Q. 1020, 1024 (Cal. 1977)); *Railway Wheels*, Unreviewed ID at 20 ("While matters of general knowledge in an industry are not eligible for trade secret protection, a specific embodiment of general concepts or a combination of elements, some or all of which may be known in the industry may be protectable as a trade secret."); *Certain Apparatus for the Continuous Production of Copper Rod*, Inv. No. 337-TA-52 ("*Copper Rod*"), Publ. No. 1017, Comm'n Op. at 43 (Nov. 23, 1979) ("It is an established principle . . . that a trade secret can exist in a combination of characteristics and components, each of which, by itself, is in the public domain, provided, however, that the unique combination of these elements is not published and affords the complainant a competitive advantage."); *Minn. Mining & Mfg. Co. v. Pribyl*, 259 F.3d 587, 595–96 (7th Cir. 2001) ("A trade secret can exist in a combination of characteristics and components, each of which, by itself, is in the public domain, but the unified process, design and operation of which, in unique combination, affords a competitive advantage and is a protectable secret.").

Whether something qualifies for trade secret protection is an issue of fact to be assessed under flexible considerations. Restatement (Third) of Unfair Competition § 39

cmt. d. ("The existence of a trade secret is properly considered a question of fact to be decided by the judge or jury as fact-finder"); 1 Roger M. Milgrim & Eric E. Bensen, Milgrim on Trade Secrets, § 1.03 ("Fundamentally, existence of a trade secret is a question of fact for determination of the trier of fact"). Precedent confirms this blackletter principle. *Furmanite Am., Inc. v. T.D. Williamson, Inc.*, 506 F. Supp. 2d 1134, 1141 (M.D. Fla. 2007) ("Courts are extremely hesitant to grant summary judgment regarding the fact-intensive questions of the existence of a trade secret or whether a plaintiff took reasonable steps to protect its trade secrets."); *Learning Curve Toys, Inc. v. PlayWood Toys, Inc.*, 342 F.3d 714, 723 (7th Cir. 2003) (whether a trade secret exists "requires an ad hoc evaluation of all the surrounding circumstances"); *Del Monte Fresh Produce Co. v. Dole Food Co.*, 136 F. Supp. 2d 1271, 1292–93 (S.D. Fla. 2001) (affirming trade secret status was a factual question, and could not be resolved without a factual record).

The value of a trade secret process lies not only in the discrete components of the process but also in the fact that those components – even if otherwise publicly available – have been selected and brought together as part of a commercially viable process. The Federal Circuit explained:

> [Defendant] argues, nonetheless, that the Polycon process is not a trade secret. He asserts that the "batch sheets . . . are nothing more than a compilation of reactions, each of which is well-known to the art and documented in the literature." [Defendant] fails to acknowledge that it is this very "compilation of reactions"—along with information about the ingredients and procedures used in them—that is the trade secret. Even if [Defendant] were correct in his assertion that all the reactions used in the Polycon process were individually well-known in the art, that would not preclude the existence of a trade secret in the *compilation* of processes:

> "A trade secret can exist in a combination of characteristics and components, each of which, by itself, is in the public domain, but the unified process, design and operation of which, in unique combination, affords a competitive advantage and is a protectable secret."

Syntex Ophthalmics, *Inc. v. Novicky*, 745 F.2d 1423, 1434 (Fed. Cir. 1984), *vacated on other grounds*, 470 U.S. 1047 (1985) (brackets omitted) (quoting *Imperial Chem. Indus. Ltd. v. Nat'l Distillers & Chem. Corp.*, 342 F.2d 737, 742 (2d Cir. 1965)); *see*, *e.g.*, *Copper Rod*, Comm'n Op. at 43; *Pribyl*, 259 F.3d at 596; *Norbrook Labs*, 297 F. Supp. 2d at 484-85 (discounting defendant's expert's analysis, where it "focused not on whether [the ex-employee] had contributed to [defendant's] development of the [manufacturing] method, but rather on whether there was anything secret about [plaintiff's manufacturing] method"); *Salsbury Labs., Inc. v. Merieux Labs., Inc.*, 735 F. Supp. 1555, 1569 (M.D. Ga. 1989) (holding that the production process as a whole constituted a trade secret and explaining that "[a]t each individual step of the process, there are a variety of alternatives that could be selected for use. [Plaintiff], through much research and experimentation, chose specific ingredients, specific amounts of each ingredient, specific methods, and specific ways in which to employ each method, at each individual step in the . . . production process."), *aff'd in relevant part*, 908 F.2d 706 (11th Cir. 1990).

Trade secret protection is not eviscerated even when the defendant "'could' have divined" the information from a public patent. *Monovis, Inc. v. Aquino*, 905 F. Supp. 1205, 1228 (W.D.N.Y. 1994). Even though "[i]tems such as [a patent] were publicly available," such items "were by no means obvious; they were not accompanied by instructions explaining where they were useful and where they were not, or what particular elements they described were relevant and helpful and which were not, or

indeed why they should be selected over some other publicly available information." *Id*. Reconstruction by hindsight is irrelevant to defining what is and is not a trade secret and to the question of misappropriation. *Merck & Co. v. SmithKline Beecham Pharm. Co.*,, No. C.A. 15443-NC, 1999 WL 669354 (Del. Ch. Aug. 5, 1999), *aff'd*, 746 A.2d 277 (Del. 2000) ("Because a process consisting entirely of generally known elements is protectable as a trade secret, the value of trade secrets would be lost if a defendant could obtain the process, learn thereby the important choices made by the trade secret owner at various process steps, use the information gained for its benefit, and avoid liability by then saying that the particular information used is 'published.'") (citation omitted).

B. Unfair Acts

As applied at the Commission, misappropriation of trade secrets "is a method of unfair competition defined by the common law." *Rubber Resins*, Comm'n Op. at 9 (Jan. 15, 2014) (EDIS Doc. ID No. 528759). Paragraph (a)(1)(A) of section 337 governs the importation of articles derived from common law forms of unfair competition:

> Unfair methods of competition and unfair acts in the importation of articles (other than articles provided for in subparagraphs (B), (C), (D), and (E), into the United States, or in the sale of such articles by the owner, importer, or consignee, the threat or effect of which is —
>
> > to destroy or substantially injure and industry in the United States;
> > to prevent the establishment of such an industry; or
> > to restrain or monopolize trade and commerce in the United States.

19 U.S.C. § 1337(a)(1)(A). Therefore, there is a requirement that the complainant demonstrate the existence of a domestic industry and an actual substantial injury or the threat of substantial injury to said domestic industry. *Rubber Resins*, Comm'n Op. at 10.

A "single federal standard," rather than the law of a particular state, applies to investigations into trade secret misappropriation under section 337. *TianRui*, 661 F.3d at 1327. Sources of applicable guidance include the Restatement of Unfair Competition, the Uniform Trade Secrets Act, and federal common law, as set forth in Commission decisions. *See id*. at 1327–28 ("Fortunately, trade secret law varies little from state to state and is generally governed by widely recognized authorities such as the Restatement of Unfair Competition and the Uniform Trade Secrets Act."); *id*. at 1328 (referring to the "generally understood law of trade secrets, as reflected in the Restatement, the Uniform Trade Secrets Act, and previous Commission decisions under section 337"). The Federal Circuit noted that the Commission has long interpreted section 337 to apply to trade secret misappropriation. *Id*. at 1326, *citing*, *inter alia*, *Sausage Casings*, USITC Publ. No. 1624 (Dec. 1984).

The elements of trade secret misappropriation are: "(1) the existence of a process that is protectable as a trade secret (*e.g.*, that is (a) of economic value, (b) not generally known or readily ascertainable, and (c) that the complainant has taken reasonable precautions to maintain its secrecy); (2) that the complainant is the owner of the trade secret; (3) that the complainant disclosed the trade secret to respondent while in a confidential relationship or that the respondent wrongfully took the trade secret by unfair means; and (4) that the respondent has used or disclosed the trade secret causing injury to the complainant." *Rubber Resins*, Comm'n Op. at 10 (*citing Sausage Casings*, ID at 361). Misappropriation must be proven by a preponderance of the evidence. *See Certain Crawler Cranes and Components Thereof*, Inv. No. 337-TA-887, ID at 132 (July 11, 2014) (EDIS Doc. ID No. 539295).

"Use" of a trade secret can occur when goods that embody a trade secret are marketed, the trade secret is employed in manufacturing or production, or is relied on to assist or accelerate research or development. RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 40, Comment c (1995). "The unauthorized use need not extend to every aspect or feature of the trade secret; use of any substantial portion of the secret is sufficient to subject the actor to liability." *Id*. Such use "need not use the trade secret in its original form." *Id*. "[A]n actor is liable for using the trade secret with independently created improvements or modifications if the result is substantially derived from the trade secret." *Id.*; *Mangren Research & Dev. Corp. v. Nat'l Chem. Co., Inc.*, 87 F.3d 937, 944 (7th Cir. 1996) ("[I]f trade secret law were not flexible enough to encompass modified or even new products that are substantially derived from the trade secret of another, the protections that law provides would be hollow indeed.").

C. Domestic Industry

1. Existence of a Domestic Industry

To obtain relief in a section 337 investigation asserting unfair acts such as trade secret misappropriation, a complainant must show that there is "an industry" in the United States subject to the threat or effect of substantial injury or destruction from "[u]nfair methods of competition and unfair acts in the importation of articles." 19 U.S.C. § 1337(a)(1)(A).

In a non-statutory IP case, the Commission may consider a broad range of elements in evaluating whether a domestic industry exists beyond those set forth in subsection 337(a)(3). *TianRui*, 661 F.3d at 1335–37; *Certain Hand Dryers and Housings for Hand Dryers* ("*Hand Dryers*"), Inv. No. 337-TA-1015, Comm'n Op. at 4 ("[T]here is

no requirement to show investments in the section 337(a)(3) categories to establish a violation of section 337(a)(1)(A).”). For example, the Commission has not limited its analysis to investments in manufacturing but has credited investments in R&D as well, including for facilities where R&D is conducted and R&D personnel. *See Rubber Resins ID* at 623–24 (crediting investments “in domestic research and development” in a trade secret case). In *Railway Wheels*, a domestic industry was found to exist based in part on investments in three facilities where research and development was conducted, as well as employment of personnel working on research and development. *Railway Wheels*, Unreviewed ID at 80–81. In that case, the R&D expenditures were not related to the trade secrets that were allegedly misappropriated. *Id*. at 75–81.

The statutory language and legislative history of section 337 further confirm that investments in R&D should be credited towards the establishment of the domestic industry in non-statutory IP cases. The 1988 amendments removed the injury requirement for statutory IP cases, but required that complainants establish the existence of a domestic industry through specified types of investments relating to the intellectual property (*i.e.*, the economic prong). *TianRui*, 661 F.3d at 1335–36. For non-statutory IP cases, the amendments still required that injury be shown, but did not alter the definition of existing industry, which did not specify factors like “plant and equipment” that needed to be shown for the domestic industry to be considered in existence. *Id*.; *Hand Dryers*, Comm’n Op. at 4. Indeed, as the Federal Circuit noted in *TianRui*, “Congress recognized that prior to the 1988 Act section 337 did not define ‘industry.’” *TianRui*, 661 F.3d at 1336 (citing H.R. Rep. No. 100–576, at 634 (1988) (Conf. Rep.), *reprinted in* 1988 U.S.C.C.A.N. 1547, 1667)). Both before and after the 1988 amendments, investments in

research and development have been considered in assessing the presence of a domestic industry. *See Railway Wheels*, Unreviewed ID at 80–81; *Certain Plastic Food Storage Containers*, Inv. No. 337-TA-152, Initial Determination at 76 (Apr. 13, 1984) (considering "the design, manufacture, distribution and sale" of products in assessing domestic industry); *Certain Doxycycline*, Inv. No. 337-TA-3, Initial Determination, 1978 WL 50686, at *6 (Oct. 31, 1978) ("Research is an essential element of the domestic industry."). Accordingly, broader categories of investments may be considered in assessing the domestic industry in non-statutory IP cases compared to statutory IP cases. The statutory language reflects this history. *Compare* 19 U.S.C. § 1337(a)(1)(A)(i) *with* 19 U.S.C. § 1337(a)(3).

"The Commission has a long history . . . of looking to 'the realities of the marketplace,' when determining the [existence of a] domestic industry in a trade secrets investigation or other investigation based on unfair acts other than traditional forms of intellectual property (such as patents)." *Railway Wheels*, Unreviewed ID at 77 (citing *Certain Apparatus for the Continuous Prod. of Copper Rod*, Inv. No. 337-TA-52, Comm'n Op. at 58–59, 1979 WL 445781, at *26 (Nov. 23, 1979)). There is no minimum monetary expenditure that a complainant must demonstrate, and there is no need to define or quantify an industry in absolute mathematical terms. *Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, Comm'n Op. at 25–26 (May 16, 2008); *Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Comm'n Op. at 39 (Aug. 1, 2007) ("[T]here is no mathematical threshold test."). When a complainant conducts operations abroad, a comparative analysis of a complainant's domestic expenditures versus its foreign expenditures, or an analysis of the value added by the

domestic activities, is conducted to determine the significance of the domestic activities. *See, e.g.*, *Certain Carburetors and Prod. Containing Such Carburetors*, Inv. No. 337-TA-1123, Comm'n Op. at 8–9, 19 (Oct. 28, 2019).

2. Substantial Injury to the Domestic Industry

In determining whether substantial injury exists, the Commission considers "a broad range of indicia, including: the volume of imports and their degree of penetration, complainant's lost sales, underselling by respondents, reductions in complainants' declining production, profitability and sales, and harm to complainant's good will or reputation." *Rubber Resins*, Comm'n Op. at 60–61. There must be a "causal nexus" between "the unfair acts of the respondents and the injury." *Id*. at 61.

In determining whether a "threat" to substantially injure exists, the "record must establish the existence of relevant conditions or circumstances from which probable future substantial injury can reasonably be inferred." *Corning Glass Works v. U.S. Int'l Trade Comm'n*, 799 F.2d 1559, 1567-68 (Fed. Cir. 1986). The Commission will consider, *inter alia*, the following factors: "(1) substantial foreign manufacturing capacity; (2) ability of imported product to undersell the domestic product; (3) explicit intention to enter into the U.S. market; (4) the inability of the domestic industry to compete with the foreign products because of vastly lower foreign costs of production and lower prices; and (5) the significant negative impact this would have on the domestic industry." *Rubber Resins*, Comm'n Op. at 64. The threatened injury must be "substantive and clearly foreseen," and there must be "a causal connection between the action of the respondents and the threatened injury." *Id*.

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V. Factual Background and Allegations

A. Daewoong-Allergan BOTOX® Distribution Agreement

In 1995, Daewoong entered into a distribution agreement with Allergan for BOTOX® in Korea. CX-2210C (Allergan-Daewoong 1995 Agreement). A decade later, [ ]. CX-0002C (Feb. 1, 2006 letter to Daewoong). Daewoong continued to distribute BOTOX® in Korea, per the terms of a new February 2008 distribution agreement. CX-2212C (Allergan-Daewoong Distribution Agreement (Feb. 27, 2008)). [ ], the parties reached an agreement whereby [ ]. CX-2213C (Allergan-Daewoong Settlement Agreement [ ].

Chang Woo Suh, a member of Daewoong's research and development planning team [ ]. RX-3159C (Suh WS) at Q/A 15–16. [ ], Dr. Suh started collecting soil samples from various locations throughout Korea, seeking to isolate *C. botulinum* bacteria from soil samples. CX-2523C (Suh Dep. Tr. (June 28, 2019)) at 197–98.

Dr. Suh acknowledged that at least according to his understanding of the terms of the agreements that Daewoong entered into with Allergan, [ ]. CX-2523C (Suh Dep. Tr. (June 28, 2019)) at 184–86; CX-2210C (1995 Allergan-Daewoong Distributorship Agreement); CX-2213C [ ] Settlement Agreement between Allergan and

Daewoong). [

]. RX-3159C (Suh WS) at Q/A 19–20.

B. Dr. Suh's Collection of Korean Soil Samples

Dr. Suh testified that [

]. CX-2522C (Suh Dep. Tr. (June 27, 2019)) at 14–15, 93; CX-2523C (Suh Dep. Tr. (June 28, 2019)) at 191. Dr. Suh testified that [

]. Suh Tr. 866–867.

According to Daewoong, the Daewoong BTX strain was isolated from soil sample [ ], which was collected by Dr. Suh [ ] near the town of Yongin, Korea. [

]. CX-2522C (Suh Dep. Tr. (June 27, 2019)) at 36–38, 71–76 (discussing CX-1719 (Apr. 21, 2006 news report of Marek's disease outbreak)). However, Marek's disease is caused by a virus (*Gallid alphaherpesvirus 2* (GaHV-2)), whereas botulism is caused by *Clostridium botulinum* bacteria. *See* CX-0010C (Pickett WS) at Q/A 124. Although the symptoms of Marek's disease in poultry can mimic many of the symptoms of botulism, Marek's disease is confirmed postmortem by various tests, including tissue histology or identification of the virus by PCR. *Id*. By the time the media report of the mass slaughter was made public on April 21, 2006, scientists had already confirmed the disease outbreak as viral—Marek's disease—not bacterial (*e.g.*, botulism) in origin. *See* CX-1719.

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[

]. CX-2523C (Suh Dep. Tr. (June 28, 2019)) at 192–94. [

]. Suh Tr. 867–68 [

]. As discussed above, *C. botulinum* bacteria are anaerobic. [

]. *See* JX-0024C.73 (DWP450-REP-171, Daewoong's Botulinum Identification and Characterization Analysis Report) [

].

According to a report prepared by Daewoong in April 2015, "[

]. *Id.*

[

]. CX-2522C (Suh Dep. Tr. (June 27, 2019)) at 36–38, 71–76; CX-1719 (Marek's Disease article (April 2006)).

Dr. Ivan C. Hall collected, identified, and isolated tens of thousands of *C. botulinum* bacteria, most of which were not type A, much less even high toxin producers.

CX-0005 (Complaint Ex. X (Smith TJ declaration)). It was from these tens of thousands of isolated strains collected sometime in the 1920s or 1930s that researchers noted that one strain produced high levels of toxin. *Id*. It was from a subculture of this strain that Army scientists at Fort Detrick screened and developed the even higher toxin producing strain that is known as the Hall A hyper strain. *Id*.; JX-0124.3 (Schantz E & Johnson E (1992)). [

].

C. Daewoong's Efforts to License a BTX Product or Obtain a Commercially Viable *C. botulinum* Type A Strain

By late 2008, when Daewoong realized that its BOTOX® distribution agreement would soon come to an end, it became a priority for Daewoong to find an alternative. RX-3159 (Suh WS) at Q/A 18. [

]. *Id*. at Q/A 19. [

]. *Id*. at Q/A 20–22. [

]. *Id*. at Q/A 23–25. [

]. CX-2180C.15 (Comprehensive Report on BTA Development Project). [

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]. *Id*. [

].

[

]. RX-3159 (Suh WS) at Q/A 26. [

]." *Id*. at Q/A 28.

[

]. *Id*. at Q/A 30.

[

]. *Id*. [

]. *Id*. [

]. CX-2180C.10 (Comprehensive Report on BTA Development Project). [

]. *Id*. at 14. [

]. CX-2523C (Suh Dep. Tr. (June 28, 2019)) at 59–61 [

]. RX-3159 (Suh WS) at Q/A 34.

[

]. *Id*. at Q/A 35. [

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]. *Id*. at Q/A 36; CX-2523C at 59–61.

[

]." RX-3159C (Suh WS) at Q/A 38. [

]. *Id*. at Q/A 40. [

] when Daewoong purportedly isolated its own *C. botulinum* strain from a soil/fecal sample collected by Dr. Suh.

According to Dr. Suh, [

]." RX-3159C (Suh WS) at Q/A 37. However, given that [

]. In fact, as Dr. Suh acknowledged, ATCC was no longer selling botulinum bacterial strains sometime prior to November 2009. CX-2523C (Suh Dep. Tr. (June 28, 2019)) at 116. [

]. *Id*. at 59–61.

D. Daewoong's Efforts to Isolate Its *C. botulinum* Type A1 Strain

[

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], when Allergan notified Daewoong of its desire to terminate the BOTOX® distribution agreement. [

]. CX-2522C at 17–18, 58–59.

The evidence shows that [

]. *See* RX-3159C (Suh WS) at Q/A 43–45. According to Dr. Suh, [

]." RX-3159C (Suh WS) at Q/A 49. [

]. CX-2523C (Suh Dep. Tr. (June 28, 2019)) at 59–61. [

].

JX-0028C.356 (Yeon Tae Jung lab notebook); CX-0869C.9 (excerpt from Yeon Tae Jung lab notebook). [

].

[

]. JX-0028C.356; CX-0869C.9. [

]. CX-2522C (Suh Dep. Tr. (June 27, 2019)) at 54–56.

[

]. *Id*. at 58–59.

[

].

[

].

E. Daewoong's Hiring of Former Medytox Employee Byung Kook Lee

Three months before [

], Byung Kook Lee entered into a consulting agreement with Daewoong. CX-2203C (Mar. 1, 2010 Daewoong-BK Lee consulting agreement). The agreement specified that the [

]

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CX-2203C.6 (§ 2(1)). According to BK Lee, Daewoong engaged him to [

]. RX-3157C (BK Lee WS) at Q/A 175–76. [

]. CX-2203C at §§ 3, 5. [

]. *Id*. at § 4(1). [

]. CX-2088C.35 (Medytox 2008 employee salary/benefits).

According to Dr. Suh, in 2010, he was facing near constant reprimands from the CEO of Daewoong at the time, Jong Wook Lee, each time they came face to face. CX-2523C (Suh Dep. Tr. (June 28, 2019)) at 204–07. Daewoong had no replacement candidate for BOTOX®, and it did not have a *C. botulinum* strain it could work with. It was during this period that Dr. Suh offered BK Lee a [

].

Three months after BK Lee signed on as a consultant to Daewoong, during this period of "extreme" "pressure and stress" that Dr. Suh endured from the CEO,

[

]. As Dr. Suh himself testified, "in 2010, the atmosphere was that because the termination [of the Allergan-Daewoong distribution agreement] was in 2008, atmosphere-wise, 'do anything' was the atmosphere." CX-2523C at 196.

VI. Unfair Acts Regarding the Asserted *C. botulinum* Strain

A. Whether a Strain of *C. botulinum* Can Be a Protectable Trade Secret

Complainants argue, in part:

> Multiple decisions support the proposition that a bacterial strain can qualify as a trade secret. In *Coamoxiclav Products*, the Commission itself permitted a trade secret claim based on the theft of a bacterial strain. *Coamoxiclav Prod. Comm'n Op.* at 1, 17. While the ALJ had ruled against the claim based on the premise that a settlement agreement (and actions taken pursuant to it) barred the claim, the Commission reversed that ruling and allowed the trade secret claim based on theft of the bacterial strain to proceed. *Coamoxiclav Prod. ID* at 6; *Coamoxiclav Prod*. *Comm'n Op*. at 10-17.
>
> In *Pioneer Hi-Bred Int'l v. Holden Found. Seeds, Inc.*, 35 F.3d 1226 (8th Cir. 1994), the court sustained a trade secret misappropriation claim against a competitor who allegedly had improperly acquired and used the plaintiff's corn seed. *Id*. at 1235-41. As the court recognized, the corn seed could be valuable and entitled to trade secret protection based on the "genetic messages" that were responsible for its characteristics. *Id.* at 1235-40. Here, as discussed, the valuable characteristics of Medytox's Hall A-hyper strain are the product of such "genetic messages" – that is, information that is encoded in the strain's genetic makeup, which provides a complete blueprint for how the organism responds to the environment, grows, produces toxin, reproduces, and survives. CX-0010C (Pickett WS) at Q/A 113.
>
> Further, while this principle would be true of the strain regardless of whether it was the product of modification or selection, as noted, the Hall A-hyper strain was specially "developed" and "screen[ed]" by US Army researchers in the 1940s. *See* CX-0010C (Pickett WS) at Q/A 73-75 (discussing JX-0124 (Johnson (1992)) and JX-0126 (Duff (1957))); Hr'g Tr. (Keim) at 203-05 (explaining that the Hall A-hyper development process would involve multiple iterations of screening, and would select for genetic mutations tied to higher toxin production).

Compls. Br. at 121–22.

Respondents argue, in part:

> All relevant legal sources governing trade secret misappropriation define a "trade secret" in the same way: "information." *See, e.g.*, Uniform Trade Secrets Act § 1(4) (as amended, 1985) ("information, including a formula, pattern, compilation, program, device, method, technique, or process[.]"); Restatement (Third) of Unfair Competition § 39 (1995) ("information that can be used in the operation of a business or other enterprise"); Restatement of the Law of Torts § 757 cmt. b (1939) ("formula, pattern, device or compilation of information"); U.S. Patent and Trademark Office, Trade Secret Policy (last visited Feb. 19, 2020), available at https://www.uspto.gov/ip-policy/trade-secret-policy ("information [that] can include a formula, pattern, compilation, program, device, method, technique or process."); 18 USC § 1839(3) (as amended 2016) ("all forms and types of financial, business, scientific, technical, economic, or engineering information[.]"). To be sure, some definitions state that "information" can include a "device", but this does not mean that *all* valuable devices (or, indeed, all valuable organisms) are trade secrets. All of the cases on this subject make plain that even where a trade secret is embodied in a physical thing, it still must satisfy the requirements for trade secret protection, *i.e.*, the information must not be known outside of the owner's company; the information must have value due to not being known outside of the company; the information must have been developed by the investment of effort or money; and the information cannot be properly acquired or duplicated by others. *Activity Tracking Devices*, ID, at *12. These requirements cannot be circumvented merely by the plaintiff pointing to the fact that all living organisms have DNA and therefore can be characterized as being "informational." If that were true, then any valuable living thing—valuable livestock, a prize winning squash—would receive trade secret protection.
>
> . . .
>
> That Medytox's strain contentions preclude trade secret protection is underscored by some of the very law cited by Complainants, *DTM Research, L.L.C. v. AT&T Corp.*, 245 F.3d 327, 330 (4th Cir. 2001). In *DTM Research*, the Fourth Circuit observed that the "inherent nature of a trade secret limits the usefulness of an analogy to property," because "[i]t is the secret aspect of the knowledge that

> provides value to the person having the knowledge" and, as a result, the law "defines a trade secret as information that has value because it is not 'generally known' nor 'readily ascertainable.'" *DTM Research*, 245 F.3d at 332 (citation omitted). Here, Medytox's bacterial strain simply is not "information" that is "secret." Indeed, it is not information at all, and even if it were, it is not a secret held uniquely by Medytox to the exclusion of others, as Medytox concedes that the strain was obtained by other pharmaceutical companies and universities, for free and without restrictions, and concedes the genome of the strain is publicly available. *See* CPB at 58-61, 66-70.
>
> Complainants and Staff cite a litany of cases they say stand for the proposition that an organism or device can be a trade secret so long as it is valuable. *See, e.g.*, CPB at 25; SPB at 50-51. That is a misstatement of the law. The case law, including the case law relied on by both Complainants and Staff, makes clear that trade secret information includes information embodied in a device, but that does not make the device itself a trade secret. Indeed, not a single one of the cases cited actually decides that a living organism can be a trade secret. In several of the cases, the courts expressly stated that they were *not* deciding that the organisms in question were trade secrets and instead expressed substantial doubt as to whether the organisms could be. *See, e.g.*, *United States v. Weiqiang Zhang*, No. 13-20134-01-CM, 2017 WL 3168955, at *2 (D. Kan. July 26, 2017) (explaining that "[t]he government was not required to prove that the stolen seeds actually contained trade secrets"); *Pioneer Hi-Bred Int'l v. Holden Found. Seeds, Inc.*, 35 F.3d 1226, 1235 (8th Cir. 1994) ("Holden does not argue on appeal that genetic messages cannot qualify as trade secrets. . . . Thus, we assume without deciding that genetic messages can qualify for trade secret status."); *Certain Coamoxiclav Prod., Potassium Clavulanate Prod., & Other Prod. Derived from Clavulanic Acid*, Inv. No. 337-TA-479, 2003 WL 1793272, at *1, Initial Determination (Mar. 6, 2003) ("*Certain Coamoxiclav Products*") (explaining that "Respondents for purposes of Motion No. 479-3, *arguendo*, conceded that: . . . SC7 was, when stolen, a trade secret owned by complainants").

Resps. Br. at 72–75.

The Staff agrees with complainants that a strain of *C. botulinum* can be a trade secret, and argues that the Medytox BTX strain is genetically distinguishable from other Hall A-hyper strains, and commercially valuable. *See* Staff Br. at 84–85.

As an initial matter, it is well established that a physical object can be considered a trade secret. Trade secret protection can extend to tangible objects such as a "formula, pattern, device or compilation of information" that is used in one's business and provides "an advantage over competitors." Restatement of the Law of Torts § 757, cmt. b; *see, e.g., United States v. Martin*, 228 F.3d 1, 11 & n.7 (1st Cir. 2000) (noting § 1839(3) "defines a 'trade secret' broadly," to include "all forms and types of . . . information . . . whether tangible or intangible") (quoting 18 U.S.C. § 1839)); *Reingold v. Swiftships, Inc.*, 126 F.3d 645, 650 (5th Cir. 1997) (fiberglass boat mold could qualify as a trade secret because it "was a 'device' that incorporated a 'pattern, . . . method, technique, or process' for the construction of ship hulls"); *Sikes v. McGraw-Edison Co.*, 665 F.2d 731, 732-34 (5th Cir. 1982) (trade secret at issue was a light-weight weed trimmer); Unif. Trade Secrets Act § 1(4) (defining trade secret to include, among other things, "device[s]"). As noted in the Restatement (First) of Torts, a characteristic of a trade secret is that it is available "for continuous use in the operation of the business." § 757 cmt. b. That is true of the Medytox Hall A-hyper strain, as it is able to be continuously used in making BTX products and provides business value as a result.

In this case, the valuable characteristics of the strain are embodied and stored in the information contained in the strain's genetic makeup, which provides a complete blueprint for how the organism responds to the environment, grows, produces toxin, reproduces and survives. *See* CX-0010C (Pickett WS) at Q/A 113. The information

encoded in the genetic material that comprises the strain, that is, its DNA, is thus the source of its commercial value as a suitable and productive part of a successful BTX manufacturing process. *See id.* at Q/A 113–14.

In *Coamoxiclav Products*, the Commission allowed a trade secret claim based on theft of a bacterial strain to proceed. *Certain Coamoxiclav Prod.*, Inv. No. 337-TA-479, Comm'n Op. at 10–17 (May 5, 2003) (EDIS Doc. ID No. 184347). In *Pioneer Hi-Bred Int'l v. Holden Found. Seeds, Inc.*, 35 F.3d 1226 (8th Cir. 1994), the court sustained a trade secret misappropriation claim against a competitor who allegedly had improperly acquired and used the plaintiff's corn seed. *Id*. at 1235–41. As the court recognized, the corn seed could be valuable and entitled to trade secret protection based on the "genetic messages" that were responsible for its characteristics. *Id.* at 1235–40; *Midwest Oilseeds, Inc. v. Limagrain Genetics Corp.*, 231 F. Supp. 2d 942, 953–54 (S.D. Iowa 2002) (defendant's improper use of the plaintiff's soybean seeds could support a trade secret misappropriation claim, as well as a conversion claim); *United States v. Weiqiang Zhang*, No. 13-20134-01-CM, 2017 WL 3168955, at *1–2 (D. Kan. July 26, 2017) (government provided sufficient evidence to show that the defendant had conspired to steal a trade secret, in violation of 18 U.S.C. § 1832(a), where the defendant improperly acquired rice seeds belonging to his employer); *American Cyanamid Co. v. Fox*, No. 5545-1962, 1964 WL 8121, at *2 (N.Y. Sup. Ct. Jan. 9, 1964) (plaintiff successfully brought trade secret misappropriation claim based in part on assertion that defendant used stolen samples of microorganisms to develop antibiotics). Here, the valuable characteristics of Medytox's Hall A-hyper strain are the product of such "genetic messages" – that is, information that is encoded in the strain's genetic makeup, which provides a complete blueprint for how

the organism responds to the environment, grows, produces toxin, reproduces, and survives. *See* CX-0010C (Pickett WS) at Q/A 113.

In addition, the Hall A-hyper strain was specially "developed" and "screen[ed]" by U.S. Army researchers in the 1940s. *See id.* at Q/A 73–75 (discussing JX-0124 (Johnson (1992)) and JX-0126 (Duff (1957))); Keim Tr. 203–205 (explaining that the Hall A-hyper development process would involve multiple iterations of screening, and would select for genetic mutations tied to higher toxin production).

The evidence establishes that the Medytox BTX strain has a unique genomic sequence, which differs from that of a publicly-known Hall A-hyper strain sequence (*i.e.*, the CP000727.1 sequence). Whether the unique sequence of the Medytox BTX strain came about from mutations that occurred naturally or whether they were "engineered" is not dispositive to the question of whether the Medytox BTX strain qualifies for trade secret status. The Medytox BTX strain has come to possess a unique genetic sequence through a selection process that occurred over decades. Between 1979, when Dr. Yang brought a vial of a Hall A-hyper strain from the University of Wisconsin – Madison, to 2003, when Medytox created its first cell bank of the Medytox BTX strain, the sum total of the various activities and exposures to different environmental conditions caused several SNPs to accumulate by selective pressure (whether or not it was inadvertent) in what is now the Medytox BTX strain. The culmination was the Medytox BTX strain, which is genetically unique from other strains, distinguishable from other Hall A-hyper strains, and is commercially valuable. It does not matter whether the Medytox BTX strain has qualities that are better than other strains or even other Hall A-hyper strains. *Dow Corning Corp. v. Jie Xiao*, 283 F.R.D. 353, 361 (E.D. Mich. 2012). The Medytox

BTX strain has commercial value, as demonstrated by its use to manufacture, *inter alia*, Meditoxin, Innotox, and MT10109L.

B. Whether Medytox's *C. botulinum* Strain Is a Protectable Trade Secret

Complainants argue that Medytox's strain is a trade secret because it is a "formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it." Restatement of the Law of Torts § 757, cmt. b.

Respondents argue that Medytox's strain is not a trade secret because it is a naturally-occurring, genetically-unmodified living organism, and as such cannot, in and of itself, be trade secret information.

1. *Sausage Casings* Factors 1 and 2: The Extent to Which the Information Is Known Outside of Complainant's Business; and the Extent to Which It Is Known By Employees and Others Involved in Complainant's Business

The first two factors of the six factors from the Restatement of Torts, cited in *Sausage Casings*, are not particularly instructive on the issue of whether a bacterial strain used to manufacture a pharmaceutical product is a trade secret. The six factors are not a six-part test, but merely "instructive guidelines for ascertaining whether a trade secret exists." *Learning Curve Toys*, 342 F.3d at 722. It is known both outside of and within Medytox that a *C. botulinum* Hall A-hyper strain is used in manufacturing Medytox's BTX products. Yet, a more relevant inquiry is whether the genetic sequence of the Medytox BTX strain is known either outside of Medytox or how many people within Medytox have knowledge of it. Until the genetic sequencing of the Medytox strain was performed by the experts for the purposes of this Investigation, it does not appear that anyone outside of Medytox knew the full sequence of the strain.

Complainants argue, in part:

> Daewoong has also suggested that the publication of the Hall A-hyper's genetic sequence operates to destroy any protection as a trade secret. Resps. Prehr'g Br. at 60. But that publication constitutes a series of nucleotides written on paper and is a mere representation of the strain's genetic code. Rather, what is needed is ***possession*** of the living organism that contains the genetic information and performs according to that information, and the ability to ***use*** that living organism to generate the neurotoxin. De novo creation of bacterial strains, such as a *C. botulinum* strain, using only a published DNA sequence is not possible using current technology, as Daewoong's expert witness effectively conceded. CX-0010C (Pickett WS) at Q/A 113-15; RX-3164C (Wilson WS) at Q/A 169 ("While in theory possible, I believe it would be extremely challenging to reproduce the bacterium itself from the published genome."). Even if doing so were theoretically possible, it certainly would not be so readily available as to render Medytox's strain without value and therefore not entitled to trade secret protection. Publication of the whole genome sequence of the Hall A-hyper strain (and one that is six SNPs different from Medytox's) accordingly does not render the strain itself with the genetic information it embodies and the ability to productively use that genetic information reasonably available to those in the trade.

Compls. Br. at 118.

Respondents argue, in part:

> Under the correct legal test, whether Medytox's strain is a trade secret turns on whether there is secret, valuable, proprietary information, *created by Medytox*, that is embodied within it. *See, e.g.*, *Activity Tracking Devices*, ID, at *12 (identifying six non-exhaustive factors for determining whether information qualifies as a trade secret: (1) the extent to which the information is known outside of complainant's business; (2) the extent to which it is known by employees and others involved in complainant's business; (3) the extent of measures taken by complainant to guard the secrecy of the information; (4) the value of the information to complainant and to its competitors; (5) the amount of effort or money expended by complainant in developing the information; and (6) the ease or difficulty

> with which the information could be properly acquired or duplicated by others.) When that test is applied to the undisputed facts of this case, the answer is plainly no.
>
> *First*, the entire genetic sequence of the Hall A-Hyper strain is public — accessible via the internet, on a website called GenBank. This alone defeats any claim that the DNA of Medytox's strain is valuable information, or that its value derives from its secrecy. According to Medytox's own expert, the Medytox subculture of the Hall A-Hyper Strain is virtually identical in its genetics to the Hall A-Hyper Strain subculture held by the U.S. government and whose genetic sequence is published in its entirety on the internet. CX-0015C.14 (Keim WS) at Q/A 45.

Resps. Br. at 78–79.

The Staff argues, in part:

> Respondents argue that the genomic sequence of the Hall A-hyper strain has been publicly available since 2007 on GenBank under accession number CP000727.1 and, thus, the Medytox BTX strain cannot be a trade secret. *See* RPB at 60. But according to Dr. Sherman, the Sanger sequencing method employed to assemble the Hall A-hyper sequence deposited as CP000727.1 is unreliable and is likely to be rife with errors. If Dr. Sherman is to be believed, then the public availability of CP000727.1 would be meaningless because no one would be able to rely on it. Of course, the Hall A-hyper strain's sequence available as CP000727.1 is reliable.

Staff Br. at 73–74 (footnote omitted).

As an initial matter, the administrative law judge notes that the genetic sequence of the Medytox BTX strain is different from the CP000727.1 sequence and different from all other strains, including those published on GenBank. Thus, the similarity of the genomic sequence of the Hall A-hyper strain to the sequence of the Medytox strain has not been established.

In addition, even if the Medytox BTX strain's genomic sequence itself were to be made public, it is unclear how a person could have exploited such information to create a

viable bacterial cell capable of reproduction, having the same genetic sequence as the Medytox BTX strain. *See* CX-0010C (Pickett WS) at Q/A 114–15. If knowledge of the Hall A-hyper strain sequence were enough to create a commercially viable strain, Daewoong would not have needed to collect random soil samples in Korea in search of *C. botulinum* type A.

Respondents further argue, in part:

> *Second*, the only allegedly secret information—the six "golden" SNPs that separate Medytox's version of the Hall A-Hyper Strain from those known to be held by others—does not have any value to Medytox or its competitors. Medytox concedes that the only genetic difference between Medytox's strain and the AMRIID Hall A-Hyper Strain published on Genbank is found in six SNPs. CX-0015C.29 (Keim WS) at Q/A 112. As such, the genetic information in those six SNPs is the only information that Medytox can claim to have "kept secret." For this information to imbue Medytox's strain with trade secret status, it must at a minimum have value to Medytox or its competitors. Yet it is undisputed that those six SNPs have no value and do not contribute to any functional difference between Medytox's strain and the AMRIID strain. Medytox's expert Dr. Pickett only provided an opinion on the value of the genetic characteristics of the entire organism. CX-0010C.22-23 (Pickett WS) at Q/A 112. Yet Dr. Pickett testified at the hearing that he had not "conducted any value analysis" on these six SNPs, separate and apart from the characteristics of the organism shared by many others who possess it. Hearing Tr. 414:9-415: 4.

Resps. Br. at 79–80.

This argument is not persuasive inasmuch as, as noted above, it is not the literal DNA sequence so much as the embodiment of the DNA in the bacteria that gives the strain its value. In any event, respondents do not dispute that the Medytox strain, and its particular six SNPs, was not publicly known.

2. *Sausage Casings* Factor 3: The Extent of Measures Taken by Complainant to Guard the Secrecy of the Information

Medytox took adequate precautions to protect its Hall A-hyper strain from disclosure. The owner of a trade secret is only required to take "reasonable measures" to safeguard its trade secrets. *See* 18 U.S.C. § 1839(3); Unif. Trade Secrets Act § 1(4); *Sausage Casings*, ID at 246–47; *Certain Rubber Resins and Processes for Manufacturing Same*, Inv. No. 337-TA-849, ID at 78, 163 (June 17, 2013) (confidentiality agreements, non-compete clauses, and document/information control policies qualify as reasonable measures) (unreviewed in relevant part).

Medytox's security with respect to its strain was extensive. During the period when the strain was held by Medytox in Dr. Jung's laboratory at Sun Moon University, it was securely kept in Medytox's separate half of the laboratory in locked storage to which only Medytox employees had keys. *See* CX-0013C (Jung WS) at Q/A 25, 53, 55; CX-0017C (Chang WS) at Q/A 29–30. Medytox facilities contained security systems including measures such as security guards, CCTV monitoring, ID scanners, manual locks, alarm systems, and steel movable walls. *See* CX-0017C (Chang WS) at Q/A 28, 31–36. Medytox heavily restricts the number of employees authorized to access and remove samples of the strain, and requires employees to state their reasons for accessing the strain in access logs maintained at each facility. *Id.* at Q/A 36.

Medytox also uses mandatory confidentiality agreements and employee onboarding trainings to explain the confidentiality obligations of every Medytox employee. *See id.* at Q/A 19–27 (explaining employee confidentiality obligations); CX-0661C (BK Lee Employment Contract); CX-2137C (BK Lee 2005 Conf. Agreement); CX-2582C (BK Lee 2007 Conf. Agreement); CX-2124C (Chang Email, 10/10/07); CX-

0699C (Medytox Sec. Pledge Agreement). Based on these agreements, trainings, and physical security measures, Medytox employees are well aware of their obligations. CX-0017C (Chang WS) at Q/A 12–15. Medytox has never transferred the strain to any third parties. CX-0013C (Jung WS) at Q/A 35.

3. *Sausage Casings* Factor 4: The Value of the Information to Complainant and to Its Competitors

Complainants argue, in part:

> Medytox's strain is commercially valuable and would be commercially valuable to Medytox's competitors. The strain is an essential element of Medytox's manufacturing process for BTX. CX-0011C (Rhee WS) at Q/A 10; CX-0013C (HH Jung WS) at Q/A 37. As Daewoong has itself recognized, obtaining a suitable strain of botulinum is one of the two "barriers to entry" into the BTX industry (the other being a manufacturing process). *See* CX-2179C.46-47 (2010 Presentation). Commercial manufacture of a BTX product requires a bacterial strain that expresses the botulinum neurotoxin ***and*** that is otherwise suitable for commercial manufacture. Not all *C. botulinum* strains are suitable for commercial manufacture. CX-0010C (Pickett WS) at Q/A 70.
>
> As Dr. Pickett testified:
>
> > Medytox's strain is valuable because it has been shown to be suitable and effective for use in the commercial manufacture of a regulatory approved and licensed botulinum neurotoxin product and is the key element of a detailed and extensive botulinum neurotoxin manufacturing process.
>
> *Id.* at Q/A 61. A strong confirmation of the commercial value of the Medytox strain is the fact that Daewoong misappropriated it – particularly if, as Daewoong now asserts, it could have instead accessed other strains without resorting to theft. *See, e.g.*, Hr'g Tr. (Resps. Opening Statement) at 99 [

].

Compls. Br. at 108–09.

Respondents argue, in part:

> *Fourth*, even putting aside that there is nothing commercially unique or valuable about Medytox's strain, it is also the case that the Hall A-Hyper strain generally does not have unique commercial value that might be necessary (though not sufficient) to claim trade secret protection. Complainants' expert Dr. Pickett claimed at trial that there are supposed commercially beneficial qualities that are unique to the Hall A-Hyper strain: high levels of toxin production, poor sporulation, and stability. CX-0010C.15 (Pickett WS) at Q/A 71. However, the record evidence does not support the claim that these are somehow unique to Medytox's strain or that they carry any special commercial value. Dr. Pickett himself conceded at the hearing that the supposedly "high levels of toxin production" in the Hall A-Hyper Strain are not necessary to make a commercially viable product, since numerous other companies market viable products using other strains. Hearing Tr. 404:23-406:12. Dr. Theresa Smith, the expert who drafted a declaration accompanying the Complaint in this case, stated that "demonstration of toxin production differences may be somewhat difficult" as between strains. CX-0005.7 (Smith Decl.). There is also no record support for Dr. Pickett's claim that Medytox's strain is a poor sporulator, since Dr. Pickett's own lab notes, when testing Medytox's strain for spores, said that he found "Many spores!" (RX-1886C.9 (Medytox Korea Litigation Spore Testing Notes)). Nor did Daewoong gain any supposed advantage from poor sporulation properties, since the FDA found that Daewoong's strain was likely not a poor sporulator and as such required Daewoong to implement process controls to ensure no spores were included in its drug substance. RX-1569C.2 (February 9, 2019 Response to IR Letter). Finally, Medytox's strain also does not come with the benefit of clear documentation of ownership, as Dr. Pickett has suggested is required. CX-0010.28-29 (Pickett WS) at Q/A 137. To the contrary, it is uncontested that Medytox did not have any documented ownership of the strain until 2017, nearly twenty years after it purportedly received the strain and a decade after it first went to market with a botulinum

> neurotoxin product. RX-2966C.7 (Medytox's Responses to Daewoong's Fourth Set of RFAs) ("Medytox admits that to the best of its knowledge and belief the first document reflecting the transfer of the Hall A-Hyper Strain from Kyu Hwan YANG to Hyun Ho JUNG is dated 2017").
>
> Underscoring the lack of any unique value to the Hall A-Hyper Strain, Complainants' expert, Dr. Pickett, conceded that other *botulinum* strains besides the Hall A-Hyper strain can be and are used by commercially viable companies to produce botulinum toxin products. *See* Hearing Tr. 405:11-407:1. This includes Merz, a highly successful company that Dr. Pickett himself previously worked for. *Id.* Indeed, Respondents have supplied evidence of *at least 30* parties on three continents who now possess, or have previously possessed, a commercially viable Hall-A Strain. *See supra* RDX-0013C.4 (Keim Cross Demonstrative) and underlying exhibits specific at Section II.E.1.d. Commercially viable Type A Strains were also available to Daewoong for purchase or license around 2010 when it first isolated its own strain. At that time, Daewoong was at an advanced stage of licensing discussion with MedExGen—a company affiliated with Hanyang University—that would have resulted in Daewoong's purchase of a commercially viable botulinum bacteria strain. RX-3159C.29 (Chang Woo SUH WS) at Q/A 29-30; RX-1863C.2 (MedExGen Discussions). There is no dispute that had Daewoong done so, it would have been able to produce an equivalent commercial product to what it is producing today. Daewoong had also been given a Type A strain by Seoul National University, so that Daewoong could perform research on that strain in its lab. RX-3159C.30 (Chang Woo SUH WS) at Q/A 34-37. Neither Complainants nor Staff have claimed that this strain could not have been commercially viable either.

Resps. Br. at 82–83.

The Staff argues, in part:

> The Medytox BTX strain is valuable for several reasons, including the fact that it is the essential ingredient in Medytox's manufacturing process for botulinum neurotoxin. CX-0011C (Rhee WS) at ¶ 10; CX-0013C (Jung WS) at ¶ 37. The Medytox strain has at least three qualities that make it particularly valuable for use in the commercial

> manufacture of a BoNT product. As Dr. Pickett explains, the Hall A-hyper strains is: (1) a particularly high toxin producer; (2) known to be stable over long periods of time; and (3) a poor sporulator that does not produce spores during the drug substance manufacturing process. CX-0010C at ¶¶ 71–72. Each of these qualities makes the Hall A-hyper strain particularly valuable in commercial settings. *Id*.
>
> Possessing a strain that produces particularly significant amounts of toxin is commercially advantageous because a high level of toxin production makes the separation and purification process of producing a BoNT product easier and safer. *Id.* at ¶ 71. Equally important is that the strain being used for commercial production be stable, *i.e.*, that it does not degenerate and become less productive over time. *Id*. If the BoNT manufacturer cannot prove the bacterial strain is stable over time, it will pose regulatory challenges, as new strains to replace the degenerated strains would have to be approved through the lengthy and expensive regulatory approval processes for the use of the new strain. *Id*. During this time, the manufacturer may not have an approved strain and, therefore, may not have a BoNT product to sell. *Id*. Thus, it is of great commercial value for a strain producing a BoNT product (and any pharmaceutical product, for that matter) to have long-term stability. Medytox has been using its strain for the commercial manufacture of BoNT products since 2006; the long term stability of the strain has been demonstrated as a practical matter.
>
> Finally, the formation of spores interferes with the manufacturing process by contaminating the manufacturing equipment and/or the pharmaceutical product. *Id*. Thus, using a strain that sporulates poorly is advantageous for the manufacturing process. *Id*. Since at least the 1980s, the Hall A-hyper strain has been reported to "rarely form[] spores," CX-1829.5 (Kihm (1988)) or to "sporulate[] very poorly." JX-0124.8 (Johnson (1992)). The poor sporulation properties of the Medytox BTX strain was also observed and confirmed by Dr. Pickett. *Id*. at ¶¶ 327–343.

Staff Br. at 76–77.

The evidence shows that Medytox's strain is commercially valuable. The strain is an essential element of Medytox's manufacturing process for BTX. CX-0011C (Rhee

WS) at Q/A 10; CX-0013C (Jung WS) at Q/A 37. Obtaining a suitable strain of botulinum is one of the two "barriers to entry" into the BTX industry (the other being a manufacturing process). *See* CX-2179C.46-47 (2010 Presentation). Commercial manufacture of a BTX product requires a bacterial strain that expresses the botulinum neurotoxin and that is otherwise suitable for commercial manufacture. Not all *C. botulinum* strains are suitable for commercial manufacture. CX-0010C (Pickett WS) at Q/A 70.

In addition, Medytox's strain has at least three qualities that make it particularly valuable for commercial manufacture. The Medytox strain is derived from the Hall A-hyper strain. CX-0013C (Jung WS) at Q/A 21, 35; CX-0015C (Keim WS) at Q/A 4. The Hall A-hyper is: (1) a particularly high toxin producer; (2) known to be stable over long periods of time; and (3) a poor sporulator that does not produce spores during the drug substance manufacturing process. Each of these qualities makes Medytox's strain especially valuable in commercial settings. *See* CX-0010C (Pickett WS) at Q/A 71–72; RX-3164C (Wilson WS) at Q/A 165[

].

Possessing a strain that produces especially large amounts of toxin is commercially advantageous because a high level of toxin production makes the separation and purification process of producing a drug substance easier and safer. *See* CX-0010C (Pickett WS) at Q/A 71. The Hall A-hyper strain (and thus Medytox's strain) was specifically developed to have high levels of toxin production. In the mid-1940s, researchers at the United States Army Medical Research Institute of Infectious Disease (USAMRIID) developed the Hall A-hyper strain by screening samples for high toxin

production. *Id.* at Q/A 73–75 (discussing JX-0124 (Johnson (1992)) and JX-0126 (Duff (1957)); Keim Tr. 203–205. That the Hall A-hyper strain produces an especially large amount of toxin has been repeatedly confirmed. *See, e.g.*, JX-0124.3 (Johnson (1992)); JX-0126.2 (Duff (1957)); RX-3551.1 (Lewis & Hill (1947)) (noting that the strain "was selected for this investigation because unpublished work by McCoy and Sarles (1943) indicated that it produced more toxin per unit of culture than any other strain tested by them"). The Hall A-hyper strain has been maintained and valued over the decades on account of its special qualities.

It is also important to be sure that the strain used for commercial production is stable, *i.e.*, that it does not degenerate and become less productive over time. *See* CX-0010C (Pickett WS) at Q/A 71. BTX strains are known to be vulnerable to degeneration, a fact that is especially problematic in the commercial space. BTX products generally receive regulatory approval based on the specific strain being used. If the producer of a BTX product were required to switch to a different strain as a result of the degeneration of its approved strain, they would likely be required to go through the lengthy and expensive regulatory approval process for use of each new strain, during which time they may not be able to produce and distribute their product. *Id.* As a result, manufacturers of BTX products have a strong incentive to ensure at the outset that the strain they receive approval for has long-term stability.

Perhaps more than any other BTX strain, the Hall A-hyper strain (from which Medytox's strain is derived) has been shown to be stable. Despite having been developed in the 1940s, the Hall A-hyper strain has continued to consistently produce high levels of toxin. The literature also indicates that the Hall A-hyper has been valued and used

specifically because it consistently produced high levels of toxin. *Id.* at Q/A 76–78 (discussing CX-1846 (Johnson (2018)). Further, there is evidence that Medytox's Hall A-hyper strain in particular has long-term stability: Medytox has been using its strain for the commercial manufacture of a BTX product for well over a decade.

The sporulation properties of a BTX strain are also an important consideration in the commercial production of a BTX product. It is advantageous to use a strain that sporulates poorly, because sporulation interferes with the manufacturing process. Regulatory requirements generally mandate that spores, which are a dormant, seed-like form of a bacteria, be removed during the manufacturing process. This requires certain specific steps in the process to ensure that spores are fully removed. Possession of a strain that does not sporulate under normal manufacture conditions obviates the need for these steps. Further, using a poorly sporulating strain could reduce the level of general environmental monitoring that might be required during the manufacturing process (due to the inherent risks posed by the spores). *See* CX-0010C (Pickett WS) at Q/A 71.

The Hall A-hyper strain is known to be poorly sporulating and not to produce spores in manufacturing conditions. Since at least the 1990s, the Hall A-hyper strain has been reported to "sporulate[] very poorly." JX-0124.8 (Johnson (1992)). Some authors have reported that they had not seen the strain form spores in their decades of working with it, CX-1885.2 (Bradshaw (2014)), while other experts, including Dr. Pickett, have opined that spores had not been observed in the Hall A-hyper strain potentially because of the specific fermentation conditions, including the medium, used. CX-1805.5 (Pickett (2014)); CX-0010C (Pickett WS) at Q/A 80–85.

4. *Sausage Casings* Factor 5: The Amount of Effort or Money Expended by Complainant in Developing the Information

Complainants argue, in part:

> Respondents contend that because Medytox itself did not genetically modify or pay for its strain, it cannot be entitled to trade secret protection and the strain is free for others to steal. RIB at 85-86. No law supports their argument that "the very act of transferring a trade secret for free destroys any claim to intellectual property protection." RIB at 86. While one cannot claim ***another's*** ideas or secrets as one's own trade secret, *see Bowser, Inc. v. Filters, Inc.*, 398 F.2d 7, 10 (9th Cir. 1968); *Callaway Golf Co. v. Dunlop Slazenger Grp. Ams., Inc.*, 318 F. Supp. 2d 205, 211 (D. Del. 2004), a trade secret plaintiff need not have created the trade secret, as opposed to obtaining it legitimately from another. *Compare* RIB at 85-86 with *Centrifugal Acquisition Corp. v. Moon*, 849 F. Supp. 2d 814, 834-85 (E.D. Wis. 2012) (ruling plaintiff could enforce trade secret acquired from original developer); *Skinner v. DVL Holdings, LLC*, No. 05-03-00785-CV, 2004 WL 113095, at *1-2 (Tex. App. Jan. 26, 2004) (same, explaining that "[i]f appellee could not protect its trade secrets, then it would have obtained nothing by virtue of the [acquisition]").
>
> Respondents selectively quote from *Bison Advisors LLC v. Kessler*, No. 14-3121 (DSD/SER), 2016 WL 4361517 (D. Minn. Aug. 12, 2016), but the lack of trade secret protection there turned on the fact that the two parties to the case had "freely traded the [allegedly trade secret] data without restriction," and without a "confidentiality agreement with respect to that data." *Id.* at *4-5. Neither *Bison Advisors* nor any other case cited by Respondents imposes a monetary-payment condition on the existence of a trade secret. There is no such requirement. *See, e.g.*, *Chadwick v. Covell*, 23 N.E. 1068, 1068-69 (Mass. 1890) (Holmes, *J.*) (trade secret defendant cannot escape liability by arguing that the plaintiff received the trade secret as a gift); 1 Milgrim on Trade Secrets § 1.02[2] (observing that it would be inconsistent with the law "to consider expense of development of a trade secret as an operative substantive element"); CIB at 111-13. The value element of trade secret status derives from its commercial value, not the cost of its development; indeed, it is black letter law that "a trade secret can be discovered fortuitously." 1 Milgrim on Trade Secrets

> § 1.02[2]; *see also* Restatement (Third) of Unfair Competition § 39 cmt. e (1995) ("A trade secret must be of sufficient value in the operation of a business or other enterprise to provide an actual or potential economic advantage over others who do not possess the information. The advantage, however, need not be great."); CIB at 111-13 (citing cases).

Compls. Reply Br. at 15–17 (footnote omitted).

Respondents argue, in part:

> *Fifth*, by its own admission, Medytox has not expended time, money, or effort to create its Hall A-Hyper Strain, or the six SNPs that purportedly distinguish Medytox's strain from others like it. *Activity Tracking Devices*, ID, at *12 (explaining that trade secret status depends upon the complainant's investment in "effort or money . . . in developing the information"). Medytox admits it did not produce its strain or genetically modify it in any way. RX-2962C.2 (Medytox's Responses to Daewoong's Second RFAs) at No. 8 (admitting that Medytox "has not intentionally genetically changed the Hall A-Hyper Strain that it uses to produce Meditoxin or MT10109L"). Medytox also acquired the strain for free. As discussed above, to even be *arguably* entitled to trade secret protection, an organism must have been produced through substantial investments of time, effort and money, to produce a commercially valuable and unique resource. *Pioneer Hi-Bred Int'l*, 1987 WL 341211, at *31, *compare with SinoMab Bioscience Ltd. v. Immunomedics, Inc.*, No. 2471-VCS, 2009 WL 1707891, at *1 (Del. Ch. Ct. June 16, 2009) (finding that the DNA sequence at issue did not qualify as a trade secret where "[i]t was a slight variation on publicly known information which Leung created in a few hours using publicly known methods."). Medytox's lack of such an investment of intellectual or monetary capital is fatal to its claim of trade secret status here.
>
> As a fallback, Complainants appear to assert that even though *Medytox* did not endow its Hall A strain with any informational value, *someone* must have. As an initial matter, this claim conflicts with the opinion of Complainants' own prior expert, Dr. Smith, who stated in her declaration that the "hyper" strain was not intentionally cultivated but instead was merely identified by two

> researchers as having greater toxin production than others. CX-0005.3 (Smith Decl.). In any event, even if it were true that someone other than Medytox bred the strain for high toxin production, development efforts by a third party cannot create trade secret protection if the plaintiff acquired the alleged trade secret for free. *See Bowser, Inc. v. Filters, Inc.*, 398 F.2d 7, 10 (9th Cir. 1968) ("[T]he ideas, formulae, designs, knowledge or skill asserted as constituting plaintiffs' trade secrets must have originated with the plaintiffs"); *Callaway Golf Co. v. Dunlop Slazenger Grp. Americas, Inc.*, 318 F. Supp. 2d 205, 211 (D. Del. 2004) (granting summary judgment to a defendant because the evidence demonstrated that the supposed trade secret at issue was not developed by plaintiff, but by a third party). Instead, the very act of transferring a trade secret for free destroys any claim to intellectual property protection. *Bison Advisors*, 2016 WL 4361517, at *4 (holding that once something has been "freely traded . . . without restriction" it cannot be a trade secret).
>
> The lack of value in Medytox's bacterial strain is confirmed by a case cited by both Complainants and Staff: *Dow Corning Corp. v. Jie Xiao*, 283 F.R.D. 353, 361 (E.D. Mich. 2012). CPB at 86; SPB at 52. In *Dow Corning* the court explicitly observed that "[t]he value of the information contained in the trade secrets . . . depends on 'how much someone is willing to pay for it.'" *Id.* (quoting Richard Posner, *Economic Analysis of Law* 10 (6th ed. 2003)). Thus, one of the best indicators of the value that Medytox places on the Hall A-Hyper Strain would be the price it paid to acquire it in the first place. Yet Medytox paid nothing. Likewise, Staff's argument that the strain had value because Dr. Yang "had paid his dues with Dr. Sugiyama" and that Dr. Sugiyama's gift of the Hall A Strain "expressed his gratitude" does not endow the strain with commercial value, and would find value in virtually object. *See* SPB at 49. And in any event, Staff's argument conflicts with Dr. Yang's own adamant testimony that he did not provide any consideration to acquire the strain from Wisconsin and did not receive any consideration whatsoever to transfer the strain to Medytox. RX-3024C.8, 21 (Kyu Hwan YANG Dep. Desg.) at 38:11-13, 83:1-3.

Resps. Br. at 84–86.

The Staff argues, in part:

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> The evidence demonstrates that Medytox has expended years of effort and considerable funds to develop commercial BoNT products using the Medytox BTX strain. CX-0013C (Jung WS) at ¶¶ 44–72. It took Medytox almost six years to both develop its manufacturing process for Meditoxin and obtain approval for the product from the relevant Korean authority, the Ministry of Food and Drug Safety (or the MFDS), from May 2000 to March 2006. *Id*. at ¶ 63. Medytox spent approximately [ ] to conduct research and development to cultivate the Medytox BTX strain and optimize a manufacturing process for the final purified toxin that is packaged as Meditoxin. *Id*. at ¶ 72. While the research and development is tied to the product manufactured from the Medytox BTX strain and not necessarily towards the creation of the strain itself, these efforts and money were expended in exploiting the Medytox BTX strain. Thus, the Staff respectfully submits they should be weighed in the consideration of whether the Medytox BTX strain has trade secret status.

Staff Br. at 79–80.

As an initial matter, there is no requirement that a trade secret be the product of any particular amount of investment. *See, e.g.*, *Learning Curve Toys, Inc. v. PlayWood Toys, Inc.*, 342 F.3d 714, 728 (7th Cir. 2003) (holding toy design to be a trade secret, notwithstanding that the cost to develop the concept was "less than one dollar and the time spent was less than one-half hour," finding that while "[a] significant expenditure of time and/or money in the production of information may provide evidence of value . . . we do not understand Illinois law to require such an expenditure in all cases"); *Chadwick v. Covell*, 23 N.E. 1068, 1068–69 (Mass. 1890) (Holmes, *J.*) (explaining that a trade secret defendant cannot escape liability by arguing that the plaintiff received the trade secret as a gift from a third party, even if the third party allegedly had no legal right to gift it); 1 Milgrim on Trade Secrets § 1.02[2] ("[S]ince it is established that a trade secret can be discovered fortuitously (ergo, without costly development), or result purely from

the exercise of creative faculties, it would appear inconsistent to consider expense of development of a trade secret as an operative substantive element.").

In this case, Dr. Kyu Hwan Yang obtained the strain from his academic mentor, Dr. Hiroshi Sugiyama, and then he passed the strain to his mentee, the founder of Medytox, Dr. Hyun Ho Jung. The strain passed without monetary compensation (at least at the time of transfer) between people connected by close relationships. Jung Tr. 332–333 ("That's the relationship, he is the master and I the pupil."). The value of a gift is not, however, diminished by the fact that it is given without monetary payment. *See, e.g.*, *Liautaud v. Liautaud*, 221 F.3d 981, 986 (7th Cir. 2000) ("The donor in a gift relationship, when the gift is trade secrets, is providing the donee with valuable advice for free.").[10]

5. *Sausage Casings* Factor 6: The Ease or Difficulty with Which the Information Could Be Properly Acquired or Duplicated by Others

Complainants argue, in part:

> Respondents next repeat their debunked argument that a Hall A-hyper strain like Medytox's was so readily available as to forfeit trade secret protection and make it open to steal without consequence. RIB at 80. Respondents are simply wrong. Trade secret protection does not require absolute secrecy or unavailability: "The requirement of secrecy is satisfied if it would be difficult or costly for others who could exploit the information to acquire it without resort to the wrongful conduct." Restatement (Third) of Unfair Competition § 39 cmt. f (1995); *see also id*. ("The theoretical ability of others to ascertain the information through proper

[10] *Dow Corning Corp. v. Jie Xiao*, 283 F.R.D. 353, 361 (E.D. Mich. 2012), which respondents cite for the proposition that "the value that Medytox places on the Hall A-Hyper Strain would be the price it paid to acquire it in the first place," Resps. Br. at 86, recites in its entirety: "The economic value of something is how much someone is willing to pay for it or, if he has it already, how much money he demands for parting with it." 283 F.R.D. at 361 (quoting Richard Posner, Economic Analysis of Law 10 (6th ed. 2003)).

means does not necessarily preclude protection as a trade secret. Trade secret protection remains available unless the information is readily ascertainable by such means."). A strain like Medytox's would have been difficult and costly to obtain, if it could be obtained at all. And indeed, that point is established by the fact that Daewoong ***did*** "resort to wrongful conduct" to obtain it.

There is no evidence that at the time Daewoong sought a strain for commercial BTX production, it could have obtained Medytox's strain or the Hall A-hyper strain at all – let alone without difficulty or cost so as to negate trade secret protection. CIB 114-16. Respondents pretend that it is "undisputed" that the strain was available from "hundreds of entities," RIB at 70-71, when in fact they have no evidence to support that contention. In fact, only five commercial companies are known to have a variation of the Hall A-hyper strain (including Medytox), CIB at 115-16, and each is commercially developing that strain and deriving value from it – none would have sold it to Daewoong, let alone given it to Daewoong without cost. For most of the entities on the long list cited by Respondents, RIB at 26-28, when the cited support is examined, there is in fact no evidence they have the Hall A-hyper strain at all. CIB at 115-16. And even if the strain were held by certain government agencies and universities, there is no evidence in the record they would or could have provided such a strain to Daewoong without cost. Further, Daewoong's own report states [

]. JX-0024C.72.

In this context, that non-commercial researchers may have exchanged the Hall A-hyper strain decades ago is of no moment. In 2010, Medytox's strain was not available in the industry. "[E]xcept by the use of improper means, there would [have been] difficulty in acquiring the information." *Certain Processes for the Manufacture of Skinless Sausage Casings and Resulting Prod.*, Inv. No. 337-TA-148, 337-TA-169, Initial Determination, 1984 WL 273789, at *94 (July 31, 1984) ("*Sausage Casings ID*") (quoting Restatement of the Law of Torts § 757 cmt. B (1939)). Against that, Respondents' citation of cases standing for the proposition that widely distributed and freely available information cannot be claimed as a trade secret is irrelevant. *Cf.* RIB at 80.

Compls. Reply Br. at 13–15.

Respondents argue, in part:

> *Third*, the Hall A-Hyper strain is not uniquely held by Medytox and does not bestow Medytox with any advantage over competitors. Instead, the strain is held by numerous commercial, academic, governmental and other entities and is available for sale on the free market. *See, e.g.*, CX-0005.3 (Smith Decl.) (stating that (1) "researchers regularly traded BoNT-producing bacterial strains [during the first part of the 20th century];" (2) "it is known that Dr. Hall sent Hall strains to various researchers during that time;" and (3) "the Hall strain was forwarded over time to multiple commercial laboratories [from the University of Wisconsin-Madison]"). Correspondence between Medytox's own lawyers and the University of Wisconsin evidences that the university "commonly traded [its bacterial] strains with other researchers outside of the University." RX-3166C.20 (Sullivan WS) at Q/A 111.
>
> The decades of unrestricted sharing of the strain, for free, defeats any claim to trade secret protection as a matter of law. "[A]s a plurality of independent use begins . . . the secret erodes. At some point there will be a sufficient number of independent users to correspond to trade use. At such time the matter is no longer secret." Roger M. Milgrim, Milgrim on Trade Secrets § 1.07[2], at 1-468.71-72 (2019); *see also Big Vision Private Ltd. v. E.I. DuPont De Nemours & Co.*, 1 F. Supp. 3d 224, 270 (S.D.N.Y. 2014) ("information that is public knowledge or that is generally known in an industry cannot be a trade secret"). As explained by the Supreme Court, "[o]nce the data that constitute a trade secret are disclosed to others, or others are allowed to use those data, the holder of the trade secret has lost his property interest in the data" and therefore trade secret protection. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1011–12 (1984); *see also Bison Advisors LLC v. Kessler*, No. CV 14-3121 (DSD/SER), 2016 WL 4361517, at *3 (D. Minn. Aug. 12, 2016) (once something has been "freely traded . . . without restriction" it cannot be a trade secret).
>
> Medytox's Hall A-Hyper strain is not a trade secret because it is commercially and functionally identical to other copies of the Hall A-Hyper strain held by commercial

> competitors now or previously in the market, including Allergan, Wako Laboratories, Mentor, Lanzhou Biological Products, Revance and Johnson & Johnson. CX-0005.4 (Smith Decl.); CX-2614C.1 (Decl. of Metabiologics, Inc.); CX-0010.18 (Pickett WS) at Q/A 87; RX-3166C.12, 18, 20-21 (Sullivan WS) at Q/A 69, 104-105, 116. Medytox's strain may also be genetically identical to the strains held by its competitors. Complainants do not even know if the Medytox strain is different by a *single* SNP from the Allergan strain or other Hall A-Hyper strains in circulation. Hearing Tr. 158:3-17.

Resps. Br. at 80–81.

The Staff argues, in part:

> Respondents, citing various documents, argue that "dozens if not hundreds of entities around the world hold substantially and commercially identical copies of the same Hall A *botulinum* strain." RIB at 71; *see* RDX-0012C.006 (listing about two dozen different documents). Respondents appear to have listed any reference to a "Hall" strain or even the possession of a botulinum neurotoxin as having the possession of "the Hall-A Strain in question." RDX-0012.006. But reference to a "Hall" strain does not necessarily refer to a Hall A-hyper strain; it could be a reference to any one of tens of thousands of *C. botulinum* strains that were collected and isolated by Dr. Ivan C. Hall from the 1920s through 1940s. CX-0005. For most of the institutions identified by Respondents as possessing "the Hall-A Strain in question," it turns out that there is actually no evidence at all of such possession. *See* CIB at 115–16. At most there are reports of possible possession of some strains (but not the Hall A-hyper strain). *Id*. Some of the institutions identified by Respondents no longer possess the Hall A-hyper strain, or the institution possessed or possesses a strain genetically distinct from Medytox's strain. *Id*.
>
> Thus, the Hall A-hyper strain is not as widespread as Respondents' unsupported allegations might suggest. Additionally, there is no evidence that Daewoong (or any other commercial entity) could ***legitimately*** obtain a Hall A-hyper strain for ***commercial*** purposes from any institution that has a confirmed Hall A-hyper *C. botulinum* strain that can trace its origins to USAMRIID. Even assuming, *arguendo*, that [

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]. There is no evidence that Daewoong would have been permitted [ ].

Staff Reply Br. at 12–13 (footnote omitted).

There is no evidence that any company currently offers the Hall A-hyper strain for sale for commercial use. As Dr. Pickett testified at the hearing, Daewoong's own documents show it was [

]. Pickett Tr. 433–437.

Respondents contend Daewoong could have purchased the Hall A-hyper strain from someone. Yet, the ability to acquire the Hall A-hyper strain in exchange for payment could serve to confirm rather than vitiate its trade secret status. Further, Daewoong's internal documents stated that [

]. JX-0024C.72 (2015 Strain Report Addendum); Pickett Tr. at 433–437. Daewoong's internal contemporaneous records further reflect that [

]. CX-2180C.9-11 (2009 BTA Memo).

[

]. *See* Compls. Br. at 116–17. [

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]. *See id.* at 117. [

]. *See id.*; CX-0010C (Pickett WS) at Q/A 92–95. [

]. CX-0010C (Pickett WS) at Q/A 92-95. [

].

[ ]. *See* Compls. Br. at 117.

[

]. *See id.*; CX-0010C (Pickett WS) at Q/A 96–98; [

]. CX-0010C (Pickett WS) at Q/A 96–98.

Although [ ], Allergan, and Medytox have versions of the Hall A-hyper strain, there is no requirement of exclusivity to a trade secret. *See, e.g.*, *Faiveley Transp. USA, Inc. v. Wabtec Corp.*, 511 F. App'x 54, 55 (2d Cir. 2013). Each of these companies derives substantial commercial value from the strain and the fact that it is not otherwise available, and there is no evidence that any of these companies would have

made the strain available to Daewoong in 2010 when it was developing DWP-450 or at any other time. *See* CX-0010C (Pickett WS) at Q/A 95–101.

Moreover, Medytox has not willingly made available its BTX strain to anyone outside of Medytox. There is no evidence that Medytox ever made its strain available for sale or available to others outside of Medytox for any purpose.

It has thus been shown that the Medytox strain is protectable as a trade secret, because: (a) the strain has economic value, (b) it is not generally known or readily ascertainable, and (c) Medytox has taken reasonable precautions to maintain its secrecy. *Rubber Resins*, Comm'n Op. at 10 (*citing Sausage Casings*, ID at 361).

C. Ownership of the Medytox Strain

Complainants argue, in part:

> The origin of Medytox's strain is no mystery. Uncontroverted testimony establishes that the strain was provided to the founder of Medytox, Dr. Hyun Ho Jung, by his academic mentor Dr. Kyu Hwan Yang. Hr'g Tr. (Jung) at 331; CX-0013C (HH Jung WS) at Q/A 21-22; CX-2606C.3 (HH Jung WS Errata); CX-0014C (KH Yang RWS) at Q/A 6-7; CX-1551C.6 (The Origin of Medytox's Botulinum Strain). As noted, Dr. Jung and Dr. Yang had a close father-son-like relationship. Hr'g Tr. (Jung) at 332. Dr. Yang expressly authorized Dr. Jung to use the strain to found Medytox in 1999. CX-0014C (KH Yang RWS) at Q/A 8. Dr. Yang had brought the strain with him to Korea when he returned from studying at the University of Wisconsin with Dr. Hiroshi Sugiyama. Dr. Sugiyama had placed no conditions on Dr. Yang's use of the strain. *Id.* at Q/A 9-11; RX-3024C (KH Yang Dep.) at 31:25-32:17; CX-2127C.18 (Docs. Re: KH Yang's Research) CX-0276C.10-11 (Medytox Strain History Report). Dr. Sugiyama is part of the first generation of researchers who worked with *C. botulinum* in the United States following World War II. RX-3024C (KH Yang Dep.) at 25:15-26:4. When Dr. Sugiyama gave the strain to Dr. Yang, in the late 1970s – over 40 years ago – there was no known commercial application for botulinum toxin; and it is therefore unsurprising that Dr.

> Yang and Dr. Sugiyama did not discuss potential commercial applications of the strain. *Id.* at 40:13-41:14.
>
> The origin of Medytox's strain is also reflected in records that span the company's history, and Respondents' argument otherwise is belied by the uncontroverted evidence. *See* Hr'g Tr. (Resps. Opening Statement) at 57 (erroneously claiming Medytox has only "oral testimony approximately 20 years after the fact"). For example, Medytox's June 14, 2001 Standards and Testing Methods submission to the Korean FDA – submitted nearly a decade before Daewoong even began developing a BTX product – recounts how Medytox obtained its strain. CX-0604C.31-32 (Origin and Development Details). The same history is recounted in Medytox's standard operating procedure dated November 5, 2008. CX-0013C (HH Jung WS) at Q/A 39-40; CX-0276C.10-11 (Medytox Strain History Report). And Dr. Yang himself said the same in a Korean television news broadcast in March 2010. CX-0013C (HH Jung WS) at Q/A 41-42; CX-2590.7 (KBS1 television broadcast interview). Throughout the company's history there was never any question as to the origin of the strain or Medytox's rights to it.

Compls. Br. at 125–26 (footnote omitted).

Respondents argue, in part:

> To establish a claim under Section 337 based on misappropriation of the strain, Medytox must prove that it is the owner or exclusive licensee of that strain. *See, e.g.*, *Certain Rubber Resins and Processes for Manufacturing Same*, Inv. No. 337-TA-849, 2013 WL 4495127, Initial Determination (June 17, 2013); *Copper Rod*, Comm'n Op., at *19; 19 C.F.R. § 210.12(a)(7) (requiring a showing that "complainant is the owner or exclusive licensee of the subject intellectual property"). It has not met that burden.
>
> . . .
>
> Medytox claims that it obtained the strain it uses to make its botulinum toxin products through a series of free, undocumented transfers among researchers going all the way back to the late 1970s. At that time, Dr. Hiroshi Sugiyama was studying *C. Botulinum* at the University of Wisconsin, alongside a student of his named Dr. Kyu Hwan YANG. According to Dr. YANG, around 1978, he

> discussed with Dr. Sugiyama his intent to continue research on *C. Botulinum* in Korea, at the Korea Advanced Institute of Science and Technology ("KAIST"). CX-0014C.12 (Kyu Hwan YANG Contingent Rebuttal WS) at Q/A 9. Dr. Sugiyama, according to Dr. YANG, allowed Dr. YANG to take multiple strains with him to Korea, which Dr. YANG did. *Id.* (emphasis added). No compensation was asked for or given. *Id*. at 12, 13 (Q/A 11, 16); RX-3019C.9 (Hyun Ho Jung Deposition Desg. Vol. 1 at 34:7-11) Dr. YANG began his research with the strains, at KAIST, in 1979. *Id*.
>
> Years later, starting in the late 1980s, Dr. Hyun Ho JUNG was a student of Dr. YANG's at KAIST, and worked with him researching *C. Botulinum*. *Id.* at 38 (Q/A 4). Dr. JUNG became a professor of Sun Moon University in 1995. *Id.* at 37 (Q/A 3). By 1996 or 1997, according to Dr. JUNG, he began "gradually transferring botulinum strains to Sun Moon University's laboratories." *Id*. A few years later, in 1999, Dr. YANG took on a new position with the KFDA; according to Dr. JUNG, it was then that Dr. YANG "entrusted" him with "all the botulinum studies in his laboratory at KAIST," including the strain at issue. *Id*. There was no compensation asked for or given. *Id*. at 44 (Q/A 28); RX-3019C.9 (Hyun Ho JUNG Dep. Desg. Vol. 1 at 34:7-11). It was not until the next year (2000) that JUNG founded Medytox. *Id*. at 37 (Q/A 1).
>
> Medytox's claim of ownership to the strain breaks down at the first link in the chain — from Sugiyama to YANG in the 1970s. There is no record whatsoever of a transfer of any proprietary interest in the strain, and Medytox's own recitation of events concedes that Dr. YANG did not pay any consideration for it. *See* CX-0014C.12 (Kyu Hwan YANG Contingent Rebuttal WS) at Q/A 9. Indeed, Dr. Yang emphasizes in his testimony that his taking of the strains was part of the "unrestricted sharing of research and resources" that occurred among researchers at the time — which contradicts any notion that he alone was the owner of the strain at that point. *Id.* at Q/A 10.

Resps. Br. at 86–89.

The Staff agrees with complainants that Medytox's strain was provided to the founder of Medytox, Dr. Jung, by his academic mentor Dr. Yang. *See* Staff Br. at 68–69.

PUBLIC VERSION

The origin of the Medytox strain can be traced back at least to the University of Wisconsin – Madison. Dr. Kyu Hwan Yang, who served as the Commissioner of the Korea Food and Drug Administration from August 2000 through March 2002, obtained masters and doctoral degrees in bacteriology from the University of Wisconsin – Madison in 1972 and 1975, respectively. *See* CX-1551C.5 (The Origin of Medytox's Botulinum Strain); CX-0014C (Yang WS) at Q/A 2. Dr. Yang conducted research on *C. botulinum*, including the Hall A-hyper strain, throughout his graduate and post-doctoral studies at the FRI, University of Wisconsin under the mentorship of Professor Hiroshi Sugiyama. CX-0014C (Yang WS) at Q/A 2, 4–5. When Dr. Yang returned to Korea in 1979 to begin his professorship at the Korea Advanced Institute for Science and Technology ("KAIST"), Dr. Sugiyama gave Dr. Yang materials, including the Hall A-hyper strain, to allow Dr. Yang to continue botulinum-related research at KAIST. *Id*. at Q/A 9; CX-0013C (Jung WS) at Q/A 7.

From 1986 to 1992, Dr. Hyun Ho Jung attended KAIST to obtain masters and doctorate degrees in microbiology, which he earned in 1988 and 1992, respectively. *See* CX-0013C (Jung WS) at Q/A 2. Dr. Jung's Ph.D. work at KAIST, which culminated in a dissertation titled "Molecular Studies on *Clostridium Botulinum* Type B Neurotoxin," was under the mentorship of Dr. Yang. *Id*. at Q/A 2, 4. In March 1995, Dr. Jung became a professor of microbiology at Sun Moon University. *Id*. at Q/A 3. Dr. Jung did not acquire a laboratory at Sun Moon until 1996; thus, Dr. Jung conducted his botulinum research mainly at KAIST, in the laboratory of his former mentor, Dr. Kyu Hwan Yang. *Id*. at Q/A 22. Gradually, as Sun Moon's microbiology graduate program matured and

Dr. Jung's laboratory became more established at the university, Dr. Jung began transferring botulinum strains from Dr. Yang's laboratory to his own at Sun Moon. *Id*.

In 1999, Dr. Yang was appointed the director of the National Institute of Toxicology Research, which was a branch of the KFDA. *Id*. at Q/A 22; CX-0014C (Yang WS) at Q/A 6. Thus, Dr. Yang needed to close his laboratory at KAIST, which included transferring his botulinum strains to Dr. Jung. CX-0013C (Jung WS) at Q/A 22, CX-0014C (Yang WS) at Q/A 6. Dr. Yang did not place any conditions on the use of the *C. botulinum* strains and consented to their transfer to and use for commercial purposes at Medytox. *See* CX-0013C (Jung WS) at Q/A 22, CX-0014C (Yang WS) at Q/A 7–8. Dr. Yang was in possession of and the owner of the *C. botulinum* strains that were transferred to Dr. Jung, and Dr. Jung took ownership of the strains, including the strain that was developed into the Medytox BTX strain. Jung Tr. 331.

Medytox has satisfied the requirements of 19 C.F.R. § 210.12(a)(7), by establishing that it is the owner of the strain or, at the very least, has a valid, legal possessory interest in the strain. *Crawler Cranes*, Comm'n Op. at 51–52 (the complainant need only show that it is the "owner of, or possesses a proprietary interest in, the trade secret").

Furthermore, Dr. Yang testified that he signed the Transfer of Strain and Research Agreement as a mere formality, inasmuch as he "had already given [his] strains to Dr. Jung in 1999, but [he] understand[s] Medytox wanted to memorialize that prior agreement." CX-0014C (Yang WS) at Q/A 18. This was done "to push back against Daewoong's attacks that [Dr. Yang] and therefore Medytox, had illegally obtained the Hall A-hyper strain." *Id*. Dr. Jung compensated Dr. Yang at a time when Medytox was

doing well financially, as Dr. Jung wanted to compensate his mentor for helping to start Medytox when it was having trouble securing funding to start the business. Jung Tr. 331–332. This was not the first time that Dr. Jung attempted to express his gratitude to his mentor. In 2004, Medytox granted Dr. Yang stock options for 2,000 shares, although at the time, the value per share was but a tiny fraction of the value in 2017, as Medytox's business became more successful over time. CX-0013C (Jung WS) at Q/A 29–31; JX-0005C (Kyu Hwan Yang Stock Option Agreement (2004)). Dr. Jung wanted to "thank [his] professor for providing Medytox with the botulinum strain it uses for production and making Medytox's success possible." CX-0013C (Jung WS) at Q/A 30.

Dr. Jung never had the impression that Dr. Yang expected to be compensated for the *C. botulinum* strains. Jung Tr. 331–332. Dr. Jung analogized his relationship with Dr. Yang "as though they were father and son." *Id*. at 332. Dr. Yang also similarly described his "relationship with Dr. Jung to be similar to a father-son relationship." CX-0014C (Yang WS) at Q/A 16. Dr. Yang further testified that "[a]sking for a written agreement, or even payment, from Dr. Jung for the transfer of the ownership of my *Clostridium botulinum* strains would have been contrary to the nature of our relationship." *Id*.

It has thus been shown that Medytox is the owner of the Medytox strain. *Rubber Resins*, Comm'n Op. at 10 (*citing Sausage Casings*, ID at 361).

D. Whether Daewoong Misappropriated the Asserted *C. Botulinum* Strain

As indicated above, complainants allege that Daewoong wrongfully obtained Medytox's strain from Dr. BK Lee. As detailed in this subsection, complainants and the Staff have shown by more than a preponderance of the evidence that Daewoong has

indeed wrongfully taken the trade secret strain by unfair means.[11] Yet, while evidence has been presented to explain complainants' suspicion and belief in his involvement in the misappropriation, it has not been established that Dr. BK Lee took the strain from Medytox and, for consideration or otherwise, gave it to Daewoong.

Incontrovertible evidence shows that Dr. BK Lee worked for Medytox, had access to Medytox's *C. botulinum* strain on many occasions,[12] and further that he left Medytox and eventually worked for Daewoong. Dr. BK Lee was not, however, the only individual to have access to the strain. It is unclear that in this case subsequent employment at Daewoong is a strong indicator of who effected the misappropriation. In fact, much is still unknown about how the misappropriation was accomplished.

A surprising amount of hearing time, and briefing allowance, was used by more than one party in an attempt to establish various habits or activities of Dr. BK Lee, some of which could have at best a tangential relationship to the question of misappropriation, including whether or not he wore a lab coat at Medytox that had pockets, and whether he was truthful about it. *See*, *e.g.*, BK Lee Tr. 625–31, 650–51; Compls. Br. at 6, 43 n.20; Compls. Reply at 18; Resps. Br. at 162–63 (subsection of brief entitled "Dr. LEE's Lab Coat Did Not Have Pockets, Further Demonstrating The Implausibility Of Medytox's Allegations"). Yet, his lab coat was not, for example, some sort of a protective suit. So, as confirmed by photographs shown to the administrative law judge during the hearing,

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[11] *See Rubber Resins*, Comm'n Op. at 10 (*citing Sausage Casings*, ID at 361).

[12] *See*, *e.g.*, CX-2066C (CBAM0301 Log); CX-0170C (CBAW0301 Log); CX-2052C.224 (BK Lee lab notebook); CX-2053C.201 (BK Lee lab notebook); CX-2054C.227, 241-242 (BK Lee lab notebook); CX-2086C.29 (CBAM0802 access log).

regardless of whether or not Dr. BK Lee's lab coat had pockets, a wearer of such a coat could access a pocket in the street clothes worn underneath. In any event, while it is clear that Dr. BK Lee had access to Medytox's strain, no evidence was presented to show when and how a specific quantity of Medytox's strain went missing. *See*, *e.g.*, Compls. Br. at 43.

Rather, misappropriation has been shown through the genetic evidence discussed herein. The evidence shows that the strain used by Daewoong is remarkably similar to that maintained by Medytox as a trade secret. Furthermore, complainants and the Staff through, among other things, expert testimony, have established that the similarities between the strains used at Medytox and Daewoong did not occur by coincidence. The burden of establishing trade secret misappropriation falls on complainants. The evidence presented by complainants, and the other parties, reasonably points only to a finding of misappropriation.

1. DNA Fingerprinting Evidence

Complainants argue, in part:

> [T]he DNA evidence establishes that the Medytox and Daewoong strains share six distinctive mutations – unique DNA fingerprints – that are not found in ***any*** of the other publicly-known strains of *C. botulinum*. The possibility of this occurring by chance is infinitesimally small – less than one in the number of stars in the universe. *Id.* at Q/A 50. The DNA data thus proves conclusively that the Medytox and Daewoong strains are a match.
>
> Still further, in contrast to distantly-related strains of *C. botulinum* that can be separated by tens of thousands of mutations, Medytox and Daewoong strains are separated by only a handful of mutations that arose after the Daewoong strain was separated from the Medytox strain – further confirming their close relationship. *Id.* at Q/A 51-52.

. . .

Dr. Keim used DNA fingerprinting to analyze whether the Daewoong strain was obtained from the Medytox strain. This method entails examining the complete composition of DNA in an organism, referred to as its "genome." Because the technique looks at the entire genome, it is commonly referred to as whole genome sequencing or "WGS" for short. The details of the technique are set out in Dr. Keim's witness statement and summarized below. *See* CX-0015C (Keim WS) at Q/A 21-34, 58-81.

. . .

Dr. Keim found that out of more than 200 strains of *C. botulinum* that are represented in GenBank, the Hall A-hyper strain, Medytox strain, and Daewoong strain all inherited a shared pattern of mutations, which confirm that the Medytox strain came from the Hall A-hyper, and the Daewoong strain came from the Medytox strain. In other words, Daewoong obtained its strain from Medytox. CX-0015C (Keim WS) at Q/A 47.

In terms of the simplified phylogenetic tree shown above, the Hall A-hyper would be analogous to Strain 1, the Medytox strain would be analogous to Strain 2, and the Daewoong strain would be analogous to Strain 3. *Id*. Just as Strain 2 and Strain 3 in the simplified phylogenetic analysis were connected by a shared "informative" SNP, the Medytox and Daewoong strains are linked by six shared informative SNPs, which are not found in any publicly available *C. botulinum* genome. *Id.* at Q/A 47, 112. As noted, the chances of this six-SNP pattern occurring by chance in both the Daewoong and Medytox strains is infinitesimal, so low as to be effectively impossible. *Id.* at Q/A 48-53, 117.

In addition to a unique pattern of six shared SNPs when compared to other strains, the Daewoong and Medytox strains are practically identical to one another. This is fundamentally inconsistent with Daewoong's claim that it found its strain in the soil, given that the Medytox strain and Hall A-hyper were both developed in the laboratory. Hr'g Tr. (Keim) at 203-4 (describing development of Hall A-hyper in the laboratory), 307 (describing development of six shared SNPs in the Medytox strain during lab passage). Depending on which sample from the Medytox cell banks is

> compared to the Daewoong strain, the number of SNPs separating the Medytox strain and the Daewoong strain ranges from six to thirteen SNPs out of approximately 3.7 million bases. CX-0015C (Keim WS) at Q/A 52. When one compares unrelated strains of *C. botulinum*, they can easily be separated by tens of thousands of SNPs. *Id*. To have only six to thirteen SNPs, out of a genome of approximately 3.7 million nucleotide positions, shows that the two strains are extremely closely related. *Id.*

Compls. Br. at 59–70 (footnote omitted).

Respondents argue, in part:

> Dr. Keim's data and analysis do not support his conclusion that the Daewoong strain is derived from the Medytox strain. First, contrary to his witness statement, Dr. Keim reluctantly admitted on cross examination that the "six shared SNPs" he identified do not show that Daewoong obtained its strain from Medytox. Second, in concluding that the Daewoong strain came from Medytox, Dr. Keim fell victim to the exact same problem that plagued the anthrax investigation he testified about at length in his witness statement: the "reference population" he used to compare the Medytox and Daewoong strains was woefully incomplete and does not permit the extreme conclusion he drew about the source of Daewoong's strain. Third, Dr. Keim's reliance on two additional shared SNPs (which he claims derive from "variants" in Medytox's CB19 and potentially CBAM0301 cell banks) suffers from the same fundamental problem, and is likewise inconclusive and unreliable. Finally, key and undisputed differences between the Daewoong and Medytox strains confirm that the Daewoong strain does not come from Medytox.
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> . . .
>
> The "six golden SNPs" did not withstand cross examination. The gravamen of Complainants' strain misappropriation theory is a phylogenetic analysis performed by its DNA expert, Dr. Paul Keim, who purports to show that the Daewoong and Medytox strains "share six distinctive mutations, unique DNA fingerprints that are not found in any other known *C. botulinum* strain," which "does not leave any doubt that the Daewoong strain came from Medytox." Hearing Tr. 11:15-21. In his witness statement,

Dr. Keim took the extreme position that these six shared SNPs, "***standing alone***," are "distinctive DNA fingerprints" whose "presence…***conclusively*** demonstrates that the Daewoong strain was derived from the Medytox strain." CX-0015C.16, 37, 42-43 (Keim WS) at Q/A 56, Q/A 142, Q/A 166 (emphasis added). In reaching this opinion, Dr. Keim compared the six SNPs "against the 222 published genomes of *C. botulinum*" and determined that they were not found in any other published genome. *Id.* at 15 (Q/A 49). In its opening statement, Complainants counsel doubled down on these opinions, arguing that the "six golden SNPs…show the match between Medytox and Daewoong" (Hearing Tr. 29:10-14) and that they "are not found in any other known *C. botulinum* strain." Hearing Tr. 11:15-21. According to Complainants, these "six golden SNPs" do "not leave any doubt that the Daewoong strain came from Medytox." Hearing Tr. 11:15-21.

Medytox's reliance on the "six golden SNPs" fell apart during cross examination. On cross examination, Dr. Keim reluctantly admitted that these six SNPs do not mean that Daewoong's strain came from Medytox because they could also be found in any of the dozens of other known Hall A-Hyper strains, including any number of strains held by or derived from the University of Wisconsin ("UW"). At the hearing, Dr. Keim admitted that if the six shared SNPs were also found in the Wisconsin strain, "it would be impossible for [him] to distinguish which one [the Daewoong strain] came from." Hearing Tr. 159:8-14. Thus, Dr. Keim's analysis does not establish that the six shared SNPs are found only in Daewoong and Medytox, as opposed to every other Hall A-Hyper strain derived from the University of Wisconsin. The six shared SNPs do nothing to set the Medytox and Daewoong strains apart from the dozens (and potentially hundreds) of other Hall A-Hyper strains that are held in collections around the world, and they do not show that Daewoong obtained its strain from Medytox as opposed to some other source. *See* Hearing Tr. 400:20-24 ("**Q.** You [Dr. Pickett] -- it's impossible to know every single holder of the Hall A-hyper strain? **A.** Yes. **Q.** You would agree with that; right? **A.** Yes."); CX-0005.6 (Smith Decl.).

In his own words, Dr. Keim acknowledged on cross examination that the six shared SNPs were "like bread crumbs back to the University of Wisconsin." *Id.* at 307:14-20. That is all his analysis purports to show: that the six

> shared SNPs arose sometime after the Hall A-hyper strain arrived at the University of Wisconsin by at least the early 1970s. That is not enough to show that Daewoong obtained its strain from Medytox.
>
> Indeed, Dr. Keim's reluctant admission at the hearing is consistent with a declaration he submitted in support of Medytox's Supplement to the Citizen Petition requesting that "any BLA application for botulinum toxin product, including the Evolus BLA, include a single nucleotide polymorphism ('SNP') analysis of the whole genome sequence ('WGS') of the C. botulinum strain to establish its source and identity." FDA-2017-P-6745-0008, at *1 (May 7, 2018), available at https://www.regulations.gov/ document?D=FDA-2017-P-6745-0008, exhibitized as RX-1969.1. (Medytox Supplement to the US FDA Citizen Petition). In his supporting declaration—which Medytox also submitted in support of its filings to compel DNA testing in this Investigation—Dr. Keim admitted that "[t]o perform the analysis, the WGS [whole genome sequence] of the Medytox Hall strain, ***its ancestor strain from the University of Wisconsin-Madison***, ***one or more subcultures of the University of Wisconsin-Madison strain or the archival Medytox strain stocks***, and the Daewoong strain stocks should be performed and SNPs compared." Keim Decl. (Ex. 8 to Complainants' Mot. for Leave to File Reply (Mot. No. 1145-006)) at 3; RX-1969.9 (Medytox Supplement to the US FDA Citizen Petition). As explained in detail below, that is exactly what Dr. Keim failed to do here.

Resps. Br. at 92–95 (footnote omitted).

The Staff argues, in part:

> Respondents do not challenge the fact that the Medytox and Daewoong BTX strains share six SNPs in common that are not present in the whole genome sequence deposited as accession number CP000727.1 in GenBank of the Hall A-hyper strain held at USAMRIID. *See generally* RIB. And they cannot challenge this because their expert, Dr. Sherman, simply refused to accept that the Sanger method derived whole genome sequence for CP000727.1 assembled by a team from, *inter alia*, USAMRIID and Los Alamos National Laboratories as an accurate sequence, and never performed any comparisons of the Medytox and

> Daewoong BTX genomic sequences to the Hall A-hyper sequence. RX-3165C (Sherman WS) at ¶ 196; CX-2516C (Sherman rebuttal report) at ¶ 38. Respondents were unable to overcome the overwhelming evidence that the Medytox and Daewoong both share the same SNPs that distinguish them from the Hall A-hyper strain from which the Medytox BTX strain is derived (and all other known *C. botulinum* type A strains), and the fact that there are as few as four, perhaps as many as six, SNPs between the Medytox and Daewoong BTX strains.

Staff Reply Br. at 9–10.

The administrative law judge finds that the Medytox and Daewoong strains share distinctive DNA fingerprints, six SNPs, that confirm they are a match. CX-0015C (Keim WS) at Q/A 16, 50, 117-18; CX-2603.1 (Keim WS errata).

Dr. Keim identified six SNPs shared by the Medytox and Daewoong BTX strains that are unique to those two strains and distinguishes them from all other known sequenced *C. botulinum* strains. Moreover, these six SNPs do not exist in the Hall A-hyper strain from which the Medytox BTX strain is derived. The possibility of two unrelated strains sharing the same six identical SNPs at the exact same nucleotide positions along a DNA sequence of nearly 3.7 million nucleotides is effectively impossible. CX-0015C (Keim WS) at Q/A 117 ("If instead one were to consider instead the hypothesis that six shared SNPs could arise by chance and coincidence, the probability is so low as to be effectively impossible. The possibility of a single mutation arising by chance in two genomes, in exactly the same position in a strand of 3.7 million positions, is extraordinarily low – less than one in a few million. For two genomes to share six instances of such a shared unique mutation at precisely the same positions is even more unlikely to occur by chance."); *see* Section I.E (Technological Background).

Respondents' expert, Dr. Sherman, initially asserted that Dr. Keim's analysis of the Daewoong and Medytox sequences was erroneous, because Dr. Keim only found 21 SNPs between the Daewoong and Medytox genomes. *See* CX-2516C (Sherman Rebuttal Expert Report) at Q/A 84. The real number, Dr. Sherman asserted, was 145 SNPs and 21 insertions and deletions ("indels," for insertions and deletions)—for a total of 166—between the Medytox and Daewoong genomes. *Id.* However, after Dr. Keim served his review of Dr. Sherman's analysis, Dr. Sherman had to agree with Dr. Keim at least in part regarding the identification of false positive SNPs in Dr. Sherman's earlier analysis. *See* RX-3165C (Sherman WS) at Q/A 87. Dr. Sherman now states there are a total of only 28 SNPs and indels between the Medytox and Daewoong genomes, not his original identification of 166 SNPs and indels. *Id.* at Q/A 89. Dr. Sherman essentially admits that 138 out of 166 SNPs and indels that he initially identified were erroneous.[13]

The evidence demonstrates Dr. Keim's analysis to be more reliable. The evidence relating to six particular single nucleotide polymorphisms or SNPs establishes that the Daewoong strain is derived from the Medytox strain.

2. The Phylogenetic Analysis

Complainants argue, in part:

[13] Dr. Sherman does not explicitly disagree with Dr. Keim's conclusion that the Medytox and Daewoong strains share six identical SNPs when compared to the Hall A-hyper strain. Dr. Sherman dismisses the six SNPs as being "hardly dispositive of anything." RX-3165C (Sherman WS) at Q/A 130. Dr. Sherman consistently asserted that no comparison of any genome sequence to the Hall A-hyper strain could be made because the whole genome sequence done by Sanger methods by USAMRIID and the Los Alamos National Laboratory could not be trusted. Dr. Sherman criticizes the more than 200 genomes of *C. botulinum* in the GenBank database that Dr. Keim analyzed and considered for his phylogenetic analysis as "incomplete," because "[t]here is nothing representative or comprehensive about these genomes." *Id.*

> Dr. Keim's phylogenetic analysis is shown in Figures 6, 7, 8, and 13 of his Report. CX-0015C (Keim WS) at Q/A 99-116; CX-2603.2 (Keim WS errata); CX-2592C (Exhibit 15 to Keim Report, containing phylogenetic trees). Figure 6 starts with the largest number of strains to illustrate the overall diversity of *C. botulinum*, and the successive trees focus more narrowly on the strains that are most closely related to the Medytox and Daewoong strains. Figures 8 and 13 show the relationship between the Hall A-hyper, Medytox, and Daewoong strains.
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> . . .
>
> To recap, the phylogenetic tree traces the history of the Daewoong strain. The Medytox and Daewoong strains share 33 distinctive SNPs with the Hall A-hyper strain. The Medytox and Daewoong strains also share the six distinctive SNPs that accumulated in the Medytox strain after it separated from the Hall A-hyper strain. And finally, the Daewoong genome has an additional six SNPs that arose after it separated from the Medytox strain. *Id.* at Q/A 112.
>
> . . .
>
> In sum, phylogenetic analysis provides the answer to the question presented: the Daewoong strain was obtained from the Medytox strain. And the Medytox strain in turn came from the Hall A-hyper strain.

Compls. Br. at 70–74 (footnote omitted).

Respondents argue, in part:

> Dr. Keim's phylogenetic analysis is flawed and, by his own admission, the six golden SNPs are inconclusive. As demonstrated above, the minor variant data is no more conclusive and does not provide a reliable basis for Dr. Keim's conclusions. But the problem for Dr. Keim is not only that his analysis is incomplete and unreliable, but that his conclusion of theft stands in direct contradiction with the numerous quantitative and qualitative differences between Daewoong's and Medytox's strains. It is largely if not entirely undisputed that there are at least 30 genetic differences—SNPs, insertions and deletions—that differentiate the Daewoong strain from the closest Medytox strain. RX-3165C.23 (Sherman WS) at Q/A 89 (identifying at least 28 SNPs and indels); Hearing Tr. 222:13-19

> (identifying two additional 16s rRNA SNPs not found by Dr. Sherman). These differences are powerful evidence that the Daewoong strain *cannot* be derived from the Medytox strain, because the number and type of mutations is simply too great to have plausibly occurred in a regular lab environment, in which mutations are extremely uncommon. Dr. Keim has not explained how the mutations at issue here—several of which occurred in highly conserved regions that mutate only over a *very long* time frame outside of the lab environment—can be explained by his hypothesis that the Daewoong strain was derived from Medytox's strain just ten years ago. The now discredited six golden SNPs and the indeterminate minor variant data is simply insufficient to overcome the strong evidence of genetic difference.

Resps. Br. at 128.

The Staff argues, in part:

> Daewoong has represented that its strain was isolated from the soil; the genetic analysis performed by Drs. Keim and Sherman disproves that. The question to be answered in this Investigation is not whether we can definitively rule out whether the Daewoong strain could be derived from the Allergan strain, [ ], or any other strain. Daewoong cannot be allowed to represent to the Korea and U.S. FDAs that its bacteria comes from the soil, but then argue that Medytox can not prove its case because Medytox has not disproven that the Daewoong strain was not misappropriated from someone else. The genetic analysis confirms that the Daewoong strain is derived from the Medytox strain. The only relevant argument that Daewoong might be able to raise would be ***if*** the Allergan strain or any of the other laboratory strains has the same or very similar genetic sequence as the Medytox or Daewoong strains. However, as Dr. Keim testified, such similarities would not put more distance in the relative positions of the Daewoong and Medytox strains in the phylogenetic tree; the fact that other strains could have identical or very similar genetic sequences to the Medytox or Daewoong strains does not alter the fact that the Daewoong strain is derived from the Medytox strain. Keim Tr. at 167:18–169:23 ("Q. Let me ask it a different way. If you had more data, is it possible you'd have much greater distance between the Daewoong strain and the Medytox strain, putting aside the major/minor allele issue? A. **No,**

> **absolutely not**.") (emphasis added). The DNA sequencing analysis is virtually indisputable; the Daewoong strain is derived from the Medytox strain and all circumstantial evidence points to Daewoong having misappropriated Medytox's BTX strain and other Medytox trade secrets. The scientific and genetic evidence establishes to a virtual certainty that Daewoong's strain could not have been isolated from the wild in a soil sample.

Staff Reply Br. at 65–66.

The administrative law judge finds that the Medytox strain and the Daewoong strain have a shared pattern of mutations, which confirms that the Medytox strain came from the Hall A-hyper strain, and that the Daewoong strain came from the Medytox strain. *See* CX-0015C (Keim WS) at Q/A 47.

In addition to a unique pattern of six shared SNPs when compared to other strains, the Daewoong and Medytox strains are otherwise largely identical to one another. These facts undercut Daewoong's claim that it found its strain in the soil, especially in view of the fact that the Medytox strain and the Hall A-hyper strain were both developed in the laboratory. Keim Tr. 203–204 (describing development of the Hall A-hyper strain in the laboratory), 307 (describing development of six shared SNPs in the Medytox strain during lab passage).

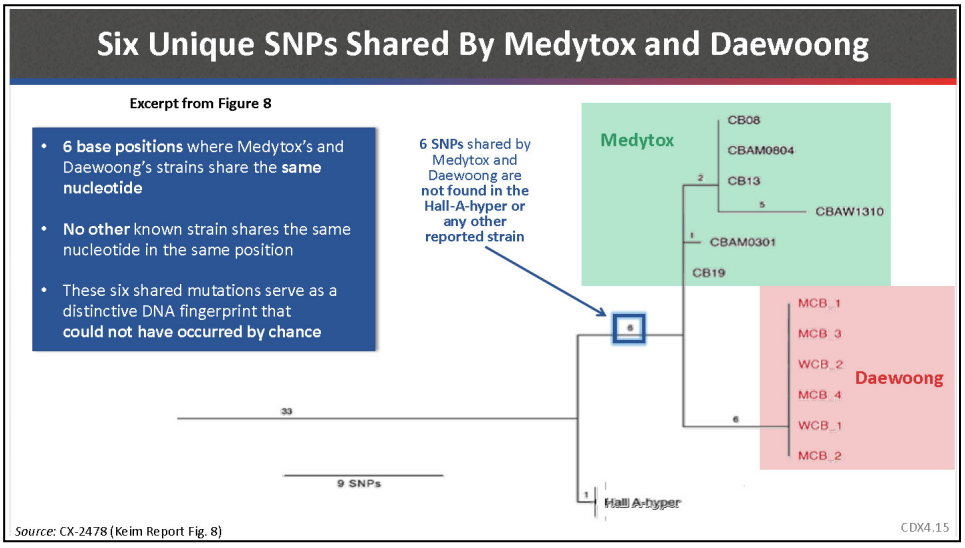
Samples from the Medytox cell banks and samples from the Daewoong cell banks may differ by a number of SNPs ranging from a minimum of six SNPs to a maximum of thirteen SNPs, out of approximately 3.7 million bases. *See* CX-0015C (Keim WS) at Q/A 52.[14] Unrelated strains of *C. botulinum*, in contrast, can be separated by tens of

[14] There are some genetic differences among samples taken from the four different Medytox cell banks, due to factors including mutation over time and even mutation that could have occurred during the process of growing the strain to harvest the DNA for sequencing. CX-0015C (Keim WS) at Q/A 112, 120.

thousands of SNPs. *Id.* To have only six to thirteen SNPs, out of a genome of approximately 3.7 million nucleotide positions, shows that the two strains are extremely closely related. *Id.*

Dr. Keim narrowed the analysis from 202 genomes to 32 type A1 *C. botulinum* genomes, as well as three genomes recovered in Asia (Kyoto, Adk2012, and Food20). *Id.* at Q/A 106. This allows a more focused look at strains in branches neighboring the Hall A-hyper branch, as well as a sense of scale to the kinds of strains that have been isolated in Asia. This analysis uses the Hall A-hyper as a reference. *Id.* at Q/A 107.

Figure 8 of Dr. Keim's Report, which was used for demonstrative purposes during the hearing, shows the relationship between the Medytox, Daewoong, and Hall A-hyper strains. CX-0015C (Keim WS) at Q/A 112. CDX-0004C.15 (Keim WS Demonstrative Ex.) (CX-2592C) is excerpted to highlight the branch leading to the Hall A-hyper, Medytox, and Daewoong strains.



Starting from the left-hand side, a horizontal line leads to the Hall A-hyper, Medytox, and Daewoong strains. As explained in Dr. Keim's witness statement, samples were taken from multiple cell banks of Medytox and Daewoong. The Medytox cell

banks are designated with the initials for "*C. botulinum*," such as "CB19" and "CBAM0301."[15] The Daewoong cell banks are designated with "MCB" and "WCB," such as "MCB1" and "WCB1." CX-0015C (Keim WS) at Q/A 82–85.

At the top of the vertical line, there is a horizontal line branching to the right with the number "6" above it. This depicts the six shared SNPs that make up a branch leading to the Medytox and Daewoong strains. These six SNPs would have accumulated after the Medytox strain was separated from the Hall A-hyper strain because one does not see them in the published Hall A-hyper genome. No publicly-known *C. botulinum* strain has these SNPs. *Id.* at Q/A 112–16.

Moving to the right from that branch, the next vertical line reflects the Medytox cell banks. The Medytox cell banks have accumulated small differences of zero to seven SNPs among themselves, reflected as small sub-branches. Many of these apparent SNPs result from the sampling methods applied to these cell banks. For example, CBAM0301 has a single SNP not shared by any other cell bank, and which did not pass on to any of its progeny. This single SNP would have resulted from the sampling process for CBAM0301, and could be the fixation of diversity in the full master cell bank or the result of a mutation during DNA harvesting. As a result, it does not serve to differentiate

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[15] Dr. Keim's original report contained an error with respect to the way the creation of CBAM0301 was created, which Dr. Keim later corrected in his witness statement. Dr. Keim opined in his initial report that the CBAM0301 cell bank contains a mixture of major and minor variants, but a supporting declaration stated that the CBAM0301 cell bank was created by [ ]. CX-2503C.3 (Ex. 17 to Keim Report, Chang Hoon Rhee declaration (Sep. 11, 2019)). Yet, if CBAM0301 had been created by [ ], a mixture of major and minor variants should not exist. However, the actual contemporaneous document reflecting the manufacture of CBAM0301 shows that it was actually made by [ ]. *See* CX-0011C (Rhee WS) at Q/A 23; Keim Tr. 239–240.

CBAM0301 from the CB19 bank. *Id.* at Q/A 128. As Dr. Keim explained, the CBAM0301 sample is distinct because it was sampled in 2016 using single colony isolation, showing one apparent SNP that did not pass on to CB19 or any of its other progeny. Keim Tr. 181–183, 306–307.

At the bottom right are the Daewoong cell banks. The line leading to them, with a "6" on it, reflects that these cell banks have accumulated a set of SNPs after having been separated from Medytox. CX-0015C (Keim WS) at Q/A 112.

The Medytox and Daewoong strains share 33 distinctive SNPs with the Hall A-hyper strain. The Medytox and Daewoong strains also share the six distinctive SNPs that accumulated in the Medytox strain after it separated from the Hall A-hyper strain. Finally, the Daewoong genome has an additional six SNPs that arose after it separated from the Medytox strain. *Id.* at Q/A 112.

Figure 13, also used for demonstrative purposes during the hearing, is a phylogenetic tree generated using a technique called "outgroup rooting," which is an additional level of rigorous analysis that Dr. Keim conducted. *Id.* at Q/A 114–15. Figure 13 shows the same relationship among the Hall A-hyper, Medytox, and Daewoong strains as does Figure 8:

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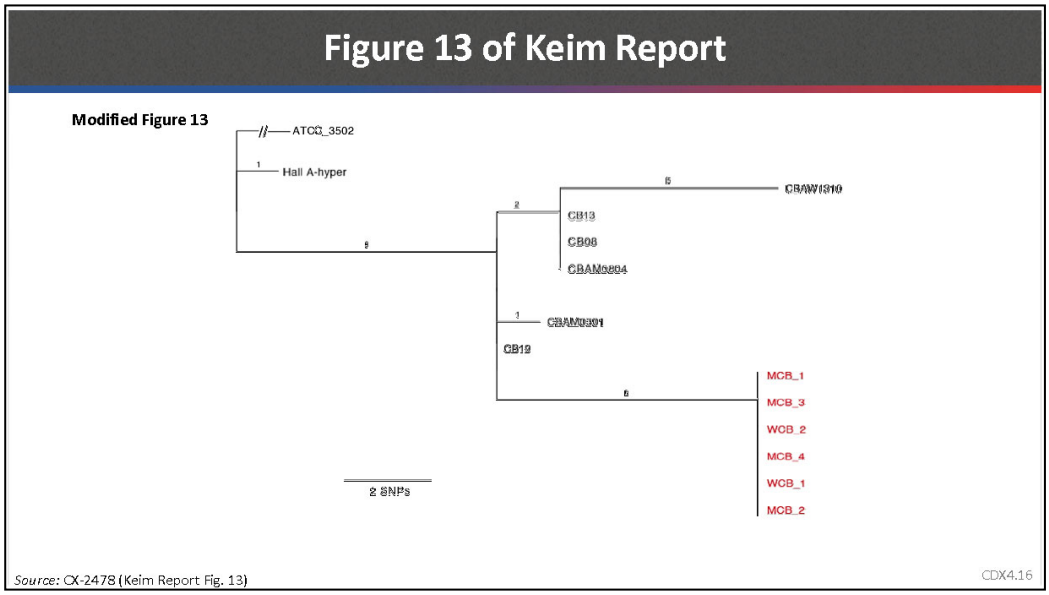


CDX-0004C.16 (Keim WS Demonstrative Ex.) (CX-2592C).

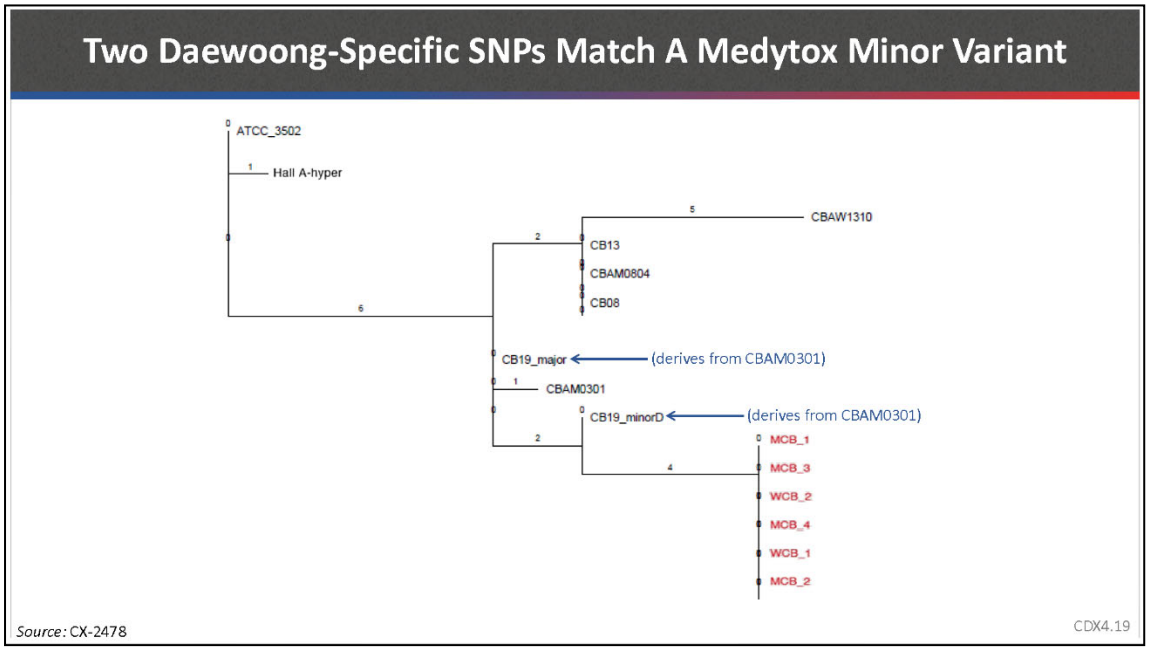
In addition to the six shared SNPs found in both the Medytox and Daewoong strains, Dr. Keim also found shared SNPs between two Medytox "minor variants" and the six SNPs that otherwise distinguish the Daewoong strain from the Medytox strain. Dr. Keim testified that the methodology employed for his work for the Department of Homeland Security to study rare variants in *B. anthracis* (anthrax) cultures to develop methods for identifying the source of evidence in criminal investigations is directly applicable to his analysis of the Medytox strain and the minor variants contained in at least one cell bank population. CX-0015C (Keim WS) at Q/A 122.

"Minor variants" refers to a subpopulation of cells within the same cell bank having mutations in the DNA that do not exist in the other cells within the same cell bank. Cell banks can develop mixtures of variants. For example, if 90% of the population of cells in a vial have a "G" in the third position of a particular gene, while the remaining 10% of the cells have an "A," the 10% with the "A" is called a minor variant and the remaining 90% with the "G" the major variant. *Id*. at Q/A 124.

What happens with these mixtures and whether they are passed along to progeny can depend on the method used to create a new cell bank from an existing cell bank, as well as the method used to grow cells for the purpose of harvesting DNA. A method called single colony isolation tends to reduce and possibly eliminate diversity and mixtures because just one colony is preserved or collected. Another method, called direct culturing or mass cell propagation, preserves the diversity and mixtures by replicating a cross-section of the original cell bank. *Id.* at Q/A 124–27.

These minor variants are present in the DNA sequencing data from one of the Medytox cell banks (CB19), which means they also exist in the cell bank from which CB19 was created. This means that the Daewoong strain has fewer differences when compared to the Medytox strain, and shares an even larger number of unique mutations, than the phylogenetic trees in Figures 8 and 13 show. *Id.* at Q/A 134–35. These are not reflected in Figures 8 or 13 because they do not show minor variants. Dr. Keim illustrated what Figure 13 would look like if the shared Medytox minor variants were included:

PUBLIC VERSION



CDX-0004C.19. As shown here, the inclusion of the two minor variants creates an even shorter branch between the Medytox and Daewoong strains. Two of the six SNPs that separate the Daewoong sample from CB19 in the original Figure 13 are actually the same two SNPs that separate the minor and major variants in CB19. The CB19 minor variant and the Daewoong strains are identical at two base positions (position numbers 544,469 and 1,525,924), and no other known sample of *C. botulinum* has the same nucleotide at these positions. This is in addition to the six SNPs already shared by all Medytox and Daewoong strain samples. The CB19 minor variant clearly became "fixed" in the Daewoong cell banks as a major variant. CX-0015C (Keim WS) at Q/A 134.

While CB19 was created in 2019, CB19 was created via [ ] from CBAM0301, and therefore would reflect the major and minor variants contained in that vial of the CBAM0301 cell bank. *Id*. at Q/A 135. The most logical conclusion is that the Daewoong strain was obtained from a sample of CBAM0301 or one of the several other Medytox cell banks that were created from CBAM0301, and the material that Daewoong

used to create their cell banks contained this minor variant we see present in CB19. *Id.* Daewoong created their cell banks via [ ], which explains how these minor variants have been fixed and preserved. RX-3167C (KY Kim WS) at Q/A 91, 96.

The depictions of phylogenetic trees prepared by complainants' expert provide a way to organize the genetic data obtained from the strains at issue, and the relationships of the strains to each other. The phylogenetic analysis shows the close relationship between the strains used by Medytox and Daewoong, and supports the conclusion that Daewoong got its strain from that used by Medytox.

VII. Unfair Acts Regarding the Asserted Manufacturing and R&D Related Information

Complainants argue, in part:

> The information about Medytox's manufacturing process that BK Lee provided to Daewoong and which Daewoong used in developing the manufacturing process for DWP-450 is a quintessential trade secret – that is, a "formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it." *Crawler Cranes ID* at 128 (quoting Restatement of the Law of Torts § 757 cmt. b); *see Syntex Ophthalmics, Inc. v. Novicky*, 745 F.2d 1423, 1433-34 (Fed. Cir. 1984) ("The set of processes and ingredients used in the manufacture of Polycon, as disclosed in the batch sheets and the FDA file, fit th[e] definition [of a trade secret]."), *vacated on other grounds*, 470 U.S. 1047 (1985); *see also supra* Section V.A.1.

Compls. Br. at 185.

Respondents argue, in part:

> None of the supposedly misappropriated steps in these three processes is a trade secret. "The subject of a trade secret must be secret, and must not be of public knowledge or of a general knowledge in the trade or business." *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 476 (1974).

> Therefore, "'[m]atters of general knowledge in the industry, or those that can be readily discerned are not eligible for trade secret protection.'" *Rubber Resins*, ID at 22. An important corollary to this principle is that, "'[m]atters disclosed in patents also will destroy an[y] claims of trade secret.'" *Rubber Resins*, ID at 22; *see, also*, *Broker Genius, Inc. v. Zalta*, 280 F. Supp. 3d 495, 518 (S.D.N.Y. 2017) (same as to patent applications).
>
> As described below, none of Medytox's claimed trade secrets is worthy of that label, because ***each and every one*** of Medytox's supposed trade secrets was disclosed in one or more of a series of publications dating which provide variants of the same fundamental protein purification process that has been studied, used and published since the 1940s: Abrams 1946 (JX-0116); Duff 1957 (JX-0126); Siegel 1979 (JX-0129); Tse 1982 (JX0120); DasGupta 1984 (JX-0118); Johnson 1996 U.S. Patent 5,512,547 (CX-1869); Malizio 2000 (JX-0119); Allergan 2008 U.S. Patent 7,354,740 (JX-0117); Allergan 2008 Canadian Patent Application 2,556,796 (RX-3277); Medytox 2009 PCT Application PCT/KR2008/0003897 (RX-1892)

Resps. Br. at 171.

The Staff argues, in part:

> Medytox alleges that Daewoong misappropriated Medytox's manufacturing processes for 900 kDa botulinum toxin products that is now used by Daewoong to manufacture, *inter alia*, DWP-450, Nabota, and Jeuveau. The evidence demonstrates that Daewoong's manufacturing processes mirrors Medytox's. Given that the only reasonably plausible conclusion is that Daewoong misappropriated the Medytox BTX strain as the starting point to isolate the Daewoong BTX strain, the Staff respectfully submits that the preponderance of the evidence also indicates that Daewoong inappropriately benefited from the misappropriation of information pertaining to aspects of Medytox's manufacturing processes as well.

Staff Br. at 102.

A. Overview of the Medytox Manufacturing Process

Medytox described its manufacturing process trade secrets as follows:

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Trade Secrets 1 and 2: The use of [

] of the manufacturing process.

Trade Secret 3: The [

]

of the manufacturing process.

Trade Secret 4: The use of [

].

Trade Secret 5: [

].

Trade Secret 6: The use of a [

].

Trade Secret 7: The use of [

].

Trade Secret 8: The use of a [

].

Trade Secret 9: The [

].

Trade Secret 10: The use of [

].

Trade Secret 11: The use of [

].

Trade Secret 12: The use of a [

].

Trade Secret 13: [ ].

See CX-2572C (Complainant Medytox's Disclosure Pursuant to Order No. 17) at 2–3; CX-0010 (Pickett WS) at Q/A 194–203.

B. Whether the Asserted Manufacturing and R&D Related Information Constitute Protectable Trade Secrets

1. *Sausage Casings* Factors 1 and 2: The Extent to Which the Information Is Known Outside of Complainant's Business; and the Extent to Which It Is Known By Employees and Others Involved in Complainant's Business

Complainants argue, in part:

> Respondents seek to defeat Medytox's trade secrets by deconstructing them to their constituent parts, arguing that each element can be found in literature. Even if this were true – and it is demonstrably not – this is a well-trodden path that courts have long ago rejected. The process itself is a trade secret, even if the elements of the process can be found in various publications. *See, e.g.*, *Copper Rod Comm'n Op.* at 43 ("[A] trade secret can exist in a combination of characteristics and components, each of which, by itself, is in the public domain, provided, however, that the unique combination of these elements is not published and affords the complainant a competitive advantage . . . ."); *Crawler Cranes ID* at 25 ("A specific embodiment of general concepts or a combination of elements, some or all of which may be known in the industry, may be protectable as a trade secret."); *3M v.*

Pribyl, 259 F.3d 587, 596 (7th Cir. 2001) **(**holding that when all materials and processes at issue "are collected and set out as a unified process, that compilation, if it meets the other qualifications, may be considered a trade secret"). Indeed, it is not only the compilation, but also Medytox's ***selection*** of particular elements to use in its manufacturing process that is itself a trade secret. *See, e.g.*, *Par Pharm., Inc. v. QuVa Pharma, Inc.*, 764 F. App'x 273, 279 (3d Cir. 2019) (holding that a single ingredient (a specific diluent) in a pharmaceutical product was a trade secret even though usage of the specific diluent was common and "was one of the two diluents hospital commonly used to dilute existing concentrated vasopressin products"); *Merck & Co. v. SmithKline Beecham Pharm. Co.*, No. C.A. 15443-NC, 1999 WL 669354, at *15 (Del. Ch. Aug. 5, 1999) ("Where at individual steps of a process there are a variety of alternatives, the choice made through much effort of specific ingredients, materials, conditions, and steps in an actual, working process constitutes a trade secret."), *aff'd*, 746 A.2d 277 (Del. 2000), *and aff'd*, 766 A.2d 442 (Del. 2000).

. . .

Importantly, nothing that was available in the public domain in 2010 provides the sort of valuable commercial information reflected in the documents BK Lee took from Medytox. No one publicly available piece of literature or patent discloses the manufacturing or characterization information contained in these documents. *See* CX-0011C (Rhee WS) at Q/A 103-11. Moreover, while the academic literature that existed in 2010 discussed pieces of information that are part of Medytox's integrated manufacturing processes, it does nothing to disclose that Medytox was using elements of it in a particular way and in a particular order to make a commercially viable clinical product. In particular, the manufacture of BTX for research purposes, which is described in academic literature, is different and less intensive than the manufacture of BTX for therapeutic (i.e., commercial) purposes, which is what is described in Medytox's trade secrets. The academic literature relating to the manufacture of BTX only provides basic, textbook-like explanations of the various steps used in the relevant process. CX-0012C (HW Kim WS) at Q/A 24. In the case of commercial manufacture, ensuring consistent, documented, and reproducible results is critical. *See, e.g.*, CX-0010C (Pickett WS) at Q/A 21, 206-10, 361. This focus

> on quality and reproducibility is reflected in the documents used to manufacture these products—including, for example, the batch records taken by BK Lee.

Compls. Br. at 185–98.

Respondents argue, in part:

> None of the supposedly misappropriated steps in these three processes is a trade secret. "The subject of a trade secret must be secret, and must not be of public knowledge or of a general knowledge in the trade or business." *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 476 (1974). Therefore, "'[m]atters of general knowledge in the industry, or those that can be readily discerned are not eligible for trade secret protection.'" *Rubber Resins*, ID at 22. An important corollary to this principle is that, "'[m]atters disclosed in patents also will destroy an[y] claims of trade secret.'" *Rubber Resins*, ID at 22; *see, also*, *Broker Genius, Inc. v. Zalta*, 280 F. Supp. 3d 495, 518 (S.D.N.Y. 2017) (same as to patent applications).
>
> As described below, none of Medytox's claimed trade secrets is worthy of that label, because ***each and every one*** of Medytox's supposed trade secrets was disclosed in one or more of a series of publications dating which provide variants of the same fundamental protein purification process that has been studied, used and published since the 1940s: Abrams 1946 (JX-0116); Duff 1957 (JX-0126); Siegel 1979 (JX-0129); Tse 1982 (JX0120); DasGupta 1984 (JX-0118); Johnson 1996 U.S. Patent 5,512,547 (CX-1869); Malizio 2000 (JX-0119); Allergan 2008 U.S. Patent 7,354,740 (JX-0117); Allergan 2008 Canadian Patent Application 2,556,796 (RX-3277); Medytox 2009 PCT Application PCT/KR2008/0003897 (RX-1892).
>
> A comparison of these public sources with Medytox's claimed trade secrets places beyond serious dispute that both the overall process and each of the individual supposed secrets were fully disclosed before 2010. Each alleged secret is discussed in detail and in order below. The three "key" steps are alleged trade secret numbers 7 [ ], 9 [ ] and 12 [ ].

Resps. Br. at 171–72.

The Staff argues, in part:

> Respondents base their defense to the misappropriation of the Medytox manufacturing processes to arguing each and every separate element could be found disclosed in published scientific literature. However, this is not the standard by which a trade secret is analyzed. "A trade secret can exist in a combination of characteristics and components, each of which, by itself, is in the public domain, but the unified process, design and operation of which, in unique combination, affords a competitive advantage and is a protectable secret." *3M*, 259 F.3d at 595–96. Respondents did not proffer any admissible evidence at the hearing of a publication or other disclosure in the public domain that combines each of the constituent elements of the Medytox manufacturing processes in the specific combination as used and asserted by Medytox. As discussed below in section V.B.4, *infra*, the Medytox manufacturing processes afford a competitive advantage to Medytox. Thus, the Medytox manufacturing processes are protectable as trade secrets.

Staff Br. at 110–11.

The trade secrets at issue are the product of Medytox's research and development efforts that included selecting each of the various elements of its manufacturing process (from among all of those that it might have selected), declining to use others (for example, [ ], and demonstrating that the selected procedures are potentially commercially viable. *See* CX-0010C (Pickett WS) at Q/A 361. Dr. Pickett explained the substantial work involved in reviewing the available literature, identifying potentially valuable information, studying and testing that information, and deciding what to incorporate (and not incorporate) into one's process. *Id.* Dr. Pickett has explained:

> [I]f a competitor were improperly given access to the results of your R&D process, that would provide substantial value to the competitor which had not been earned. To allow the competitor to escape consequences for their actions, simply because the various features of your own process were subsequently identified in the literature after the fact (and also with the benefit of having learned your own process),

> would completely disregard the efforts you had expended in the R&D process and deprive you of the protection to which you should be entitled. If this were the case, it is difficult to see how trade secrets could ever be protected in this field.

Id.; 1 Melvin F. Jager, Trade Secrets Law § 1:3 ("The encouragement of increasingly higher standards of fairness and commercial morality . . . continues to be the touchstone of trade secret law in the courts."); *Agilent Techs., Inc. v. Kirkland*, No. CIV.A. 3512-VCS, 2010 WL 610725, at *22 (Del. Ch. Feb. 18, 2010) (Strine, *J.*) (ruling that defendants misappropriated plaintiff's "bonding, slurry solvent, and multilayering techniques," even though they were not identical, where the evidence indicated that defendants – former employees of plaintiff – "could avoid testing things that would not work because they had been tried and had failed at Agilent").

Medytox has identified information and processes that have significant commercial value, reflecting years of Medytox R&D that are not publicly available and have never been publicly disclosed. CX-0011C (Rhee WS) at Q/A 47–100; CX-0010C (Pickett WS) at Q/A 231–33. That companies jealously guard and protect information relating to their manufacturing process as a valuable asset is well-accepted. *See* CX-0010C (Pickett WS) at Q/A 209; *Ferroline Corp. v. Gen. Aniline & Film Corp.*, 207 F.2d 912, 921 (7th Cir. 1953); CX-2525C (CS Kim Dep.) at 117; CX-2686C (CS Kim Dep.) at 117–19; CX-2524C (CS Kim Dep.) at 181; CX-2533C (SK Kim Dep.) at 35–37. Obtaining a competitor's R&D information, such as its batch records or characterization data, is the classic example of trade secret misappropriation, and it would provide substantial value in accelerating a company's R&D timeline. CX-0010C (Pickett WS) at Q/A 229–33, 358–62. The commercial value of a company's manufacturing process is illustrated by the fact that no company has ever published or made available its process

for manufacturing BTX products, as detailed in a batch record. CX-0010C (Pickett WS) at Q/A 229–33.[16]

Respondents did not offer any admissible evidence at the hearing of a publication or other disclosure in the public domain that combines each of the constituent elements of the Medytox manufacturing processes in the specific combination as utilized and asserted by Medytox. Respondents point to disparate literature as allegedly disclosing the specific elements of the Medytox manufacturing processes:

[
] (JX-0120); [
] (JX-0119); [ ] (JX-0128); and [ ] (JX-0129).

[
] (JX-0118); [ ] (JX-0119); [ ] (JX-0126).

[
] (JX-0120); [ ] (JX-0119); [ ] (JX-0126); and [ ] (JX-0116).

[
] (JX-0120); [
] (JX-0119).

[
] (JX-0126); and [ ] (JX-0116).[17]

[
] (JX-0119); [ ] (JX-0117).

[
] (JX-0120);

[16] Several Daewoong witnesses have described its manufacturing process in terms of a trade secret. *See*, *e.g.*, CX-2532C (JW Lee Dep.) at 121–22 (Daewoong's CEO describing the Nabota manufacturing process as "trade secret"); CX-2524C (CS Kim Dep.) at 181 (describing Daewoong's R&D as "extremely confidential information of Daewoong pertaining to its production technology, its know-how"); CX-2533C (SK Kim Dep.) at 35–37 (describing Daewoong's R&D as "trade secrets" which, "if leaked . . . would necessarily cause impact to the company").

[17] [
].

[ ] (JX-0119); and [ ] (JX-0118) [ ].

[ ] (JX-0119) [ ].

[ ] (CX-1869); [ ] (JX-0119); [ ] (JX-0117).

[ ] (JX-0119).

No single reference cited by respondents discloses each of the specific elements of the Medytox manufacturing processes. Furthermore, respondents have not asserted that any of the references disclose the specific element in the specific stage of the manufacturing process as used by Medytox.

Respondents deconstruct Medytox's trade secrets to their constituent parts, arguing that each element can be found in literature. However, it is the process as a whole that is the trade secret, even if the elements of the process can be found in various publications. *See, e.g.*, *Certain Apparatus for the Continuous Production of Copper Rod*, Inv. No. 337-TA-52 ("*Copper Rod*"), Publ. No. 1017, Comm'n Op. at 43 (Nov. 23, 1979) ("[A] trade secret can exist in a combination of characteristics and components, each of which, by itself, is in the public domain, provided, however, that the unique combination of these elements is not published and affords the complainant a competitive advantage . . . ."); *On-Line Techs, Inc. v. Bodenseewerk Perkin-Elmer GmbH*, 386 F.3d 1133, 1141 (Fed. Cir. 2004); *3M v. Pribyl*, 259 F.3d 587, 596 (7th Cir. 2001) (holding that when all materials and processes at issue "are collected and set out as a unified process, that compilation, if it meets the other qualifications, may be considered a trade secret"). Indeed, it is not only the compilation, but also Medytox's selection of particular elements to use in its manufacturing process that is itself a trade secret. *See, e.g.*, *Par Pharm., Inc.*

v. QuVa Pharma, Inc., 764 F. App'x 273, 279 (3d Cir. 2019) (holding that a single ingredient (a specific diluent) in a pharmaceutical product was a trade secret even though usage of the specific diluent was common and "was one of the two diluents hospitals commonly used to dilute existing concentrated vasopressin products").

2. *Sausage Casings* Factor 3: The Extent of Measures Taken By Complainant to Guard the Secrecy of the Information

Medytox has always closely guarded its proprietary, confidential manufacturing process information. The relevant analysis is whether "reasonable measures to keep such information secret" were taken. 18 U.S.C. § 1839(3)(A); Unif. Trade Secrets Act § 1(4)(ii) (Unif. Law Comm'n 1985); *Sausage Casings*, ID at 246–47 (citing Restatement of Law of Torts § 757 cmt. b). The steps Medytox took to protect its trade secrets included:

- Physical security measures at its facilities. *See* CX-0013C (Jung WS) at Q/A 52–56; CX-0017C (Chang WS) at Q/A 28–36.
- Confidentiality agreements and training, including requiring BK Lee to sign confidentiality agreements preventing the disclosure of "[t]echnical secrets such as manufacturing processes" and "[s]ecrets related to research, development, education, or training." CX-2137C.4 (BK Lee Confi. Agreement, 2005); CX-0661C.6 (BK Lee Employment Contract) (prohibiting employees from giving Medytox's "technical secrets including manufacturing method of a product" to "competing companies").[18]

[18] *See* CX-2582C.2 (BK Lee 2007 Conf. Agreement) (prohibiting unauthorized disclosure of Medytox's trade secrets to third parties); CX-0699C.4 (Medytox Sec. Pledge Agreement); CX-0017C (Chang WS) at Q/A 9-27; CX-2016C.26 (Medytox Orientation Material) (prohibiting working from home without "permission from the leader of your division"); CX-2017C.13 (Medytox PC Security Mgmt. Rules) ("Company related work shall be performed only inside the company. Any activity related to work cannot be performed outside of the workplace"). Though CX-2016C and CX-2017C, the copies of these policies available to Medytox when this litigation began, are dated after BK Lee's departure, they are substantially similar to the versions in place during BK Lee's employment. CX-0017C (Chang WS) at Q/A 17.

- IT security systems. *See* CX-0017C (Chang WS) at Q/A 10.

These measures are sufficient to support the conclusion that Medytox took adequate precautions to protect its trade secrets.

Medytox has employed robust physical security measures at its facilities and even maintained physical separation and security with respect to its strain and manufacturing processes during the early days of R&D conducted by Dr. Jung at Sun Moon University. *See* CX-0013C (Jung WS) at Q/A 52–56; CX-0017C (Chang WS) at Q/A 28–30.

Medytox required its employees to sign confidentiality agreements preventing the disclosure of "[t]echnical secrets such as manufacturing processes" and "[s]ecrets related to research, development, education, or training." CX-2137C.4 (BK Lee confidentiality agreement, 2005); CX-0661C.6 (BK Lee Employment Contract) (prohibiting employees from giving Medytox's "technical secrets including manufacturing method of a products" to "competing companies"); CX-2582C.2 (BK Lee 2007 Confidentiality Agreement) (prohibiting unauthorized disclosure of Medytox's trade secrets to third parties); CX-0699C.4 (Medytox Sec. Pledge Agreement).

Since 2007, Medytox has had in place robust IT security, including the Cautus-CM system that tracks employee email, and the SecuPrint system that logs employee printing. Medytox has also maintained controls that prevent employees from saving to physical storage like USB thumb drives and web-based storage like Dropbox. CX-0017C (Chang WS) at Q/A 10.

3. *Sausage Casings* Factor 4: The Value of the Information to Complainant and to Its Competitors

Medytox's manufacturing process information reflects Medytox's R&D and its decisions, following years of extensive experimentation on the optimal method for

manufacturing a commercial BTX product, about what to include in a proprietary, commercially viable manufacturing process. *See, e.g.*, *Norbrook Labs. Ltd. v. G.C. Hanford Mfg. Co.*, 297 F. Supp. 2d 463, 484-87 (N.D.N.Y. 2003) (holding that specific steps in plaintiff's method of manufacturing veterinary penicillin constituted trade secrets and explaining that "[t]he trial and error work in which [plaintiff] engaged to develop its [manufacturing] method is both evidence that the method is a trade secret, and that it is entitled to trade secret protection"), *aff'd*, 126 F. App'x 507 (2d Cir. 2005).

Medytox's manufacturing process for producing toxin from its Hall A-hyper strain and purifying it into a drug substance is valuable to Medytox, and would be valuable to its competitors. *See* CX-0012C (HW Kim WS) at Q/A 4–138; CX-0013C (Jung WS) at Q/A 44–72; CX-0017C (Chang WS) at Q/A 37–79. Medytox undertook a research and development program from August 2000 to October 2004 to develop a manufacturing process for BTX type A complex. *See* CX-0012C (HW Kim WS) at Q/A 26–47; CX-0017C (Chang WS) at Q/A 45–47, 57; CX-0013C (Jung WS) at Q/A 59–64. As a result of this effort, Medytox was allegedly able to independently develop a BTX product fit for commercial use and sale. In total, it took Medytox almost six years to develop the manufacturing process for Meditoxin and obtain regulatory approval to sell the product in Korea. *See* CX-0013C at Q/A 63. Thus, the investment in the research and development for the manufacturing processes is valuable in terms of time and effort invested by Medytox. By virtue of using Medytox's proprietary manufacturing process information and innovations, respondents gained a head start of at least 21 months in the commercial manufacture of their Accused Products. *See* CX-0010C (Pickett WS) at Q/A 325.

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4. *Sausage Casings* Factor 5: The Amount of Effort or Money Expended by Complainant in Developing the Information

In addition to the almost six years to develop the manufacturing process for Meditoxin and obtain regulatory approval to sell the product in Korea (CX-0013C (Jung WS) at Q/A 63), Medytox further estimates it spent approximately [ ] to conduct research and development to cultivate the Hall A-hyper strain and optimize a manufacturing process for the final purified toxin that is packaged into the final botulinum product of Meditoxin. *Id*. at Q/A 72.

The development of the BTX separation and purification process reflected in the Medytox Batch Record illustrates the substantial investment and effort that went into developing Medytox's manufacturing process as a whole. *See* CX-2068C (Meditoxin Batch Record); CX-2091C (Batch Record, Version No. 04); CX-2092C (Batch Record, Version No. 05). The separation and purification process, which involves separating the cultured neurotoxin complex from the undesirable substances contained in the culture medium and using a variety of chemical compounds and techniques to remove finer pollutants from the drug substance, is the most difficult portion of the drug substance manufacturing process to develop, and therefore is the most instructive (though certainly not the only) example of Medytox's extensive efforts to independently develop a BTX product fit for commercial use:

- Medytox first designed two potential methods to separate and purify the neurotoxin complex that was cultured from its *C. botulinum* strain: Method 1 and Method 2. CX-0012C (HW Kim WS) at Q/A 26; CX-2143C, CX-0164C, CX-0330C-CX-0332C, CX-2091C, CX-2102C, CX-2092C.

- Between approximately August 2000 and October 2004, Medytox ran these processes (and iterations thereof) numerous times to identify areas for improvement, including whether a different order of steps or a

different purification method altogether would produce a higher quality drug substance. CX-0012C (HW Kim WS) at Q/A 26–47; CX-0017C (Chang WS) at Q/A 45–47, 57; CX-0013C (HH Jung WS) at Q/A 59–64; CX-0136C, CX-0131C-CX-0133C, CX-0164C, CX-2143C.

- [

]. CX-0136C; CX-0136C.143-44 (Purification of BoNT/A).

- [

]. CX-0012C (HW Kim WS) at Q/A 41, 50; CX-0136C; CX-0136C.202-03 (Purification of BoNT/A).

- [

]. CX-0012C (HW Kim WS) at Q/A 41, 51, 58; CX-0136C.202-03 (Purification of BoNT-A); CX-0164C.

Dr. Seong Hun Chang and Hack Woo Kim testified that these changes were the direct result of hands-on R&D efforts by Medytox.

During this time, Medytox also conducted focused experiments to optimize the process and parameters at each point in the manufacturing process, which consisted of altering the process parameters (like [ ]) of various steps in the process to determine whether the change had a positive or negative effect on the quality of the drug substance produced. *See* CX-0012C (HW Kim WS) at Q/A 26–47; CX-0136C, CX-0131C-CX-0133C, CX-0164C, CX-2143C; CX-0136C (Purification of BoNT-A); CX-0130C (Hand-written notes); CX-0131C (SDS Page); CX-0132C (Hand-written notes); CX-0133C (Hand-written notes).

This iterative process was extremely complicated for many reasons, including the fact that a change in any step of the manufacturing process could have unexpected interactions with other steps in the process. CX-0010C (Pickett WS) at Q/A 197; CX-0012C (HW Kim WS) at Q/A 35; CX-0017C (Chang WS) at Q/A 46. Several rounds of testing of the entire process were therefore required whenever any part of any individual step was changed. CX-0012C (HW Kim WS) at Q/A 35; CX-0017C (Chang WS) at Q/A 46. The resultant drug substance also had to be tested at various points in the process after every change to ensure that that change improved the overall quality of the drug substance. CX-0012C (HW Kim WS) at Q/A 35; CX-0017C (Chang WS) at Q/A 46. In total, it took Medytox almost six years to develop the manufacturing process for Meditoxin and get regulatory approval to sell this product in Korea. CX-0013C (Jung WS) at Q/A 63. This development process alone cost Medytox approximately [

]. *Id.* at Q/A 72.

Medytox recorded the various versions of its processes in batch records. CX-0012C (HW Kim WS) at Q/A 48; CX-0017C (Chang WS) at Q/A 42. The batch record reflects not only information concerning each individual step in the manufacturing process but also how those steps fit together. CX-0010C (Pickett WS) at Q/A 206–10. In view of the years of independent development that went into creating these processes, batch records contain several elements that Medytox claims as trade secrets, such as [

]

stage. CX-0331C.54-59 (Aug. 2004 Master Batch Record). Given the value of the information contained in these documents, Medytox has never publicly disclosed these documents or the information they contain. CX-0011C (Rhee WS) at Q/A 43–45, 62–65; CX-0010C (Pickett WS) at Q/A 209.

Moreover, Medytox used the Meditoxin manufacturing process as the starting point for extensive experimentation to improve its manufacturing process, which resulted in several innovations. For example, Medytox experimented with simplifying the purification process, including by [ ]. Medytox found that this improved toxin yields. CX-0012C (HW Kim WS) at Q/A 125–29; CX-0017C (Chang WS) at 76–78; CX-0525C.6-7 (Meeting Minutes); CX-2099C.12-17 (Manuf. & Research Schedule) (comparing the June/July 2005 manufacturing process with the August 2005 manufacturing process).

These innovations also included experiments on the [ ] to optimize the potency of the neurotoxin. CX-0012C (HW Kim WS) at Q/A 115, 132. This involved, for example, [

]. *Id.* at Q/A 132–36. Ultimately, Medytox determined that [

] was an improvement. *Id.* at Q/A 132; CX-0017C (Chang WS) at 96–97.

Medytox also experimented with different ingredients for the culture medium, which consists of a liquid broth composed of nutrients for the *C. botulinum* to grow and replicate, including the [

]. CX-0012C (HW Kim WS) at Q/A 90–114; CX-0017C (Chang WS) at Q/A 70-79; CX-0141C.13-23 (Presentation for Process Improvement Action Plan); CX-

0566C.5 (Validity Confirmation Test Relating to Plant-Derived Medium); CX-2063C.21, 23 (Experimental Batch Record); CX-0042C.5 (PD Work Report).

5. *Sausage Casings* Factor 6: The Ease or Difficulty with Which the Information Could Be Properly Acquired or Duplicated by Others

No producer of commercial BTX products has made its manufacturing process publicly available, as the manufacturing process is "amongst the most closely guarded secrets of any commercial [BTX] company." *See* CX-0010C (Pickett WS) at Q/A 209. Medytox spent over four years developing its manufacturing processes for BoNT type A complex and almost six years developing the manufacturing process for Meditoxin and obtaining regulatory approval to sell the product in Korea. This weighs heavily in favor of a finding that the Medytox manufacturing processes cannot be easily acquired or duplicated by others.

The evidence thus shows that no single reference cited by respondents discloses each of the specific elements of the Medytox manufacturing processes, or the specific elements in the specific stages of Medytox's manufacturing process.

The administrative law judge finds that the Medytox process is protectable as a trade secret, because: (a) it is of economic value, (b) it is not generally known or readily ascertainable, and (c) Medytox has taken reasonable precautions to maintain its secrecy. *See Rubber Resins*, Comm'n Op. at 10 (*citing Sausage Casings*, ID at 361).

C. Ownership of the Asserted Manufacturing and R&D Trade Secrets

Medytox owns its method for producing neurotoxin complex from its Hall A-hyper strain and purifying it into a commercially viable drug substance. *See* CX-0012C (HW Kim WS) at Q/A 4–138; CX-0013C (Jung WS) at Q/A 44–72; CX-0017C (Chang WS) at Q/A 37–79. Medytox's development process began with an extensive and

documented review of available academic literature regarding isolation and purification of BTX. *See* CX-0012C (HW Kim WS) at Q/A 18. That literature review revealed that the available academic literature did not disclose a usable commercial-scale manufacturing process for BTX. CX-0012C (HW Kim WS) at Q/A 24–25. As Dr. Pickett has explained, this is because no producer of commercial BTX products has made its manufacturing process publicly available, as the manufacturing process is "amongst the most closely guarded secrets of any commercial [BTX] company." CX-0010C (Pickett WS) at Q/A 209. Accordingly, Medytox took what was available from the academic literature and began its own R&D program. That process, which is documented in contemporaneous documents produced by Medytox in this investigation, was intensive and lasted from August 2000 to October 2004. *See* CX-0012C (HW Kim WS) at Q/A 26–47; CX-0017C (Chang WS) at Q/A 45–47, 57; CX-0013C (Jung WS) at Q/A 59–64; CX-2143C, CX-0164C, CX-0330C-CX-0332C, CX-2091C, CX-2102C, CX-2092C, CX-0136C, CX-0129C-CX-0133C, CX-2138C.

Development of the BTX separation and purification process reflected in the Medytox Batch Record illustrates the substantial investment and effort that went into developing Medytox's manufacturing process as a whole. *See* CX-2068C (Meditoxin Batch Record); CX-2091C (Batch Record, Version No. 04); CX-2092C (Batch Record, Version No. 05).

Medytox recorded the various versions of its processes in batch records. CX-0012C (HW Kim WS) at Q/A 48; CX-0017C (Chang WS) at Q/A 42. The batch record reflects not only information concerning each individual step in the manufacturing process but also how those steps fit together. CX-0010C (Pickett WS) at Q/A 206–10.

These batch records contain several elements that Medytox claims as trade secrets, such as the use of [ ]. CX-0331C.54-59 (Aug. 2004 Master Batch Record). Given the value of the information contained in these documents, Medytox has never publicly disclosed these documents or the information they contain. CX-0011C (Rhee WS) at Q/A 43–45, 62–65; CX-0010C (Pickett WS) at Q/A 209.

Medytox used the Meditoxin manufacturing process as the starting point for extensive experimentation to further improve its manufacturing process, which resulted in several innovations. For example, Medytox experimented with simplifying the purification process, including by [ ]. Medytox found that this improved toxin yields. *See* CX-0012C (HW Kim WS) at Q/A 125–29; CX-0017C (Chang WS) at 76–78; CX-0525C.6-7 (Meeting Minutes); CX-2099C.12-17 (Manuf. & Research Schedule) (comparing the June/July 2005 manufacturing process with the August 2005 manufacturing process).

Medytox's innovations were recorded in documents such as the EBR, the PQP, and the attachments to the PQP. CX-0011C (Rhee WS) at Q/A 50, 92–102; CX-0017C (Chang WS) at Q/A 96. Medytox has not publicly disclosed these documents or the processes described therein. CX-0011C (Rhee WS) at Q/A 59, 100. The information contained in these documents would provide a distinct advantage to a competitor by allowing it to shortcut the usual R&D process and revealing unique details of Medytox's innovative manufacturing process. CX-0010C (Pickett WS) at Q/A 217–18, 227–28. Due to the value of such information, companies would not disclose it to competitors or

publish the results anywhere in any circumstance other than a patent application. *Id.* at Q/A 229.

The administrative law judge finds that Medytox is the owner of the trade secrets. *See Rubber Resins*, Comm'n Op. at 10 (*citing Sausage Casings*, ID at 361).

D. Whether Daewoong Misappropriated the Asserted Manufacturing and R&D Trade Secrets

Complainants argue, in part:

> The evidence regarding the origin of Daewoong's manufacturing process for DWP-450 coalesces around one conclusion: Daewoong received and relied on confidential, proprietary information concerning Medytox's drug substance manufacturing process, providing it with a substantial advantage in bringing DWP-450 to market. This follows from, among other evidence, the facts that:
>
> (1) Daewoong urgently sought out a BTX manufacturing process;
>
> (2) BK Lee had a thorough knowledge of Medytox's manufacturing trade secrets;
>
> (3) With awareness of BK Lee's knowledge of Medytox's manufacturing trade secrets, Daewoong engaged BK Lee with a contract that paid him an exceptional amount of money and required him to provide a manufacturing process to Daewoong, and the only manufacturing process information he knew came from Medytox's trade secrets;
>
> (4) Daewoong's laboratory notebooks confirm BK Lee's involvement in the development of its manufacturing process, including its first manufacturing runs;
>
> (5) Daewoong's initial manufacturing process mirrors Medytox's process for Meditoxin, and Daewoong's subsequent claimed innovations mirror Medytox's own innovations;
>
> (6) Daewoong has no contemporaneous documentation to support its claim of its supposed

> independent R&D or its purported reliance on academic articles;
>
> (7) Daewoong's claim that it relied on published academic articles to develop its manufacturing process is contradicted and precluded by its successful patent application, in which it identified none of these articles and instead claimed that its manufacturing process was novel and could not be found in the prior art; and
>
> (8) Daewoong's development team lacked any BTX-related experience or relevant expertise, and yet claims to have developed its drug product in an implausibly short period of time.

Compls. Br. at 132–33.

Respondents argue, in part:

> Even if Complainants or Staff had demonstrated that the manufacturing process documents constitute protectable trade secrets, they have failed to carry their burden that Daewoong misappropriated them. To demonstrate misappropriation, Complainants and Staff must show that Daewoong *actually used* the claimed trade secrets. *See, e.g.*, *Certain Activity Tracking Devices, Sys., & Components Thereof*, Inv. No. 337-TA-963, ID, 2016 WL 11596099, at *11 (Aug. 23, 2016) (noting that a complainant must show "'that the respondent has used or disclosed the trade secret causing injury to the complainant'"); *see also Certain Crawler Cranes and Components Thereof*, Inv. No. 337-TA-887, Comm'n Op., 2015 WL 13817116, at *22 (May 6, 2015). To carry this burden, a complainant cannot rely on "speculation and innuendo without substantial support in the record." *Activity Tracking Devices* at *17 (citing *Lucent Techs, Inc. v. Gateway, Inc*., 543 F.3d 710, 723-24 (Fed. Cir. 2008)). Where, as here, a trade secret claim is premised on a complainant's employee later working for a competitor, the ITC has held that the mere fact that a former employee "retained [a complainant's] information is not sufficient to prove that [the former employee] used it or intended to do so." *Id.* at *23. To the contrary, where a complainant claims that a former employee conveyed trade secrets to a new employer, the complainant must show that the former employee "was the conduit for such misappropriation." *Id.*

> at *17. Applying these principles to this Investigation – where Complainants have piled speculation on top of conjecture – Complainants and Staff have not met their burden to show that BK LEE *actually took*, and Daewoong *actually used*, Medytox's trade secrets.

Resps. Br. at 186–87.

The Staff agrees with complainants, arguing that the evidence demonstrates that Daewoong's manufacturing processes mirrors Medytox's. Staff Br. at 102.

At least a preponderance of the evidence shows that Daewoong inappropriately benefited from the misappropriation of Medytox's strain and information pertaining to aspects of Medytox's manufacturing process.

As discussed above, complainants allege that Dr. BK Lee played a role in the misappropriation. The evidence establishes that Dr. BK Lee had access to, and knowledge of, numerous details of Medytox's manufacturing process, and also worked with Daewoong when it was trying to develop its own process. Thus, Dr. BK Lee could have divulged trade secret information to Daewoong, although the record is not clear that he actually did so. Yet, an abundance of evidence establishes that the Daewoong process is derived from, and in many ways identical to, Medytox's trade secret process.

Indeed, three factors demonstrate that Daewoong misappropriated the manufacturing process from Medytox: (1) the similarity of Daewoong's process to Medytox's; (2) the lack of evidence of Daewoong's independent development; and (3) the implausibly fast timeline by which Daewoong achieved BTX production at commercial scale.

[

]. *See* RX-3161C (CS Kim WS) at Q/A 59–60 (citing JX-0119

(Malizio (2000)). [

]. JX-0031C (DWP450-REP-009). [

]. JX-0031C.29 (DWP450-REP-009). [

]. RX-3161C (CS Kim WS) at Q/A 59. [

]. *See* JX-0012C (DWP450-REP-033); Wilson Tr. 551–563.

Siegel deals exclusively with the culturing (*i.e.*, fermentation) stage of the production process, and does not disclose a purification process. CX-0010C (Pickett WS) at Q/A 294 (discussing JX-0129 (Siegel (1979))). [

]. CX-0010C (Pickett WS) at Q/A 294; Wilson Tr. 554–556.

[ ], but Malizio does not mention the [ ], and the extraction and purification process described by Malizio does not [ ]. CX-0010C (Pickett WS) at Q/A 294 (discussing JX-0119 (Malizio (2000))); Wilson Tr. 576–77.

Daewoong's first run of a manufacturing process in August 2010 copies the Meditoxin process, [ ]. JX-0119C.6 (Malizio (2000)); *see* CX-0010C (Pickett WS) at Q/A 294; Wilson Tr. 535, 576–77.

1. Daewoong's Manufacturing Process Shares Similarities with Medytox's Proprietary Process

Daewoong's manufacturing process [ ] substantially overlaps with Medytox's manufacturing process. The Drug Substance Manufacturing Process Development document from Daewoong's Biologics License Application is cited as an illustration of this overlap, even highlighting the [ ]. JX-0007C.7 (BLA section 3.2.S.2.6). This is illustrated in a side-by-side comparison of the two processes:

[

]

CDX-0010C.2. According to Dr. Pickett, the two processes share the following ten commonalities:

1) [

]. CX-0010C (Pickett WS) at Q/A 243–44.

2) [

]. *Id*. at Q/A 245.

3) [

]. *Id*. at Q/A 246.

4) [

]. *Id*. at Q/A 247.

5) [

]. *Id*. at Q/A 248.

6) [

]. *Id*. at Q/A 249.

7) [

]. *Id*. at Q/A 250.

8) [

]. *Id*. at Q/A 251, 253.

9) [

]. *Id*. at Q/A 252.

10) [

]. *Id*. at Q/A 254.

The similarities between the Daewoong and Medytox processes cannot be coincidence. Three key similarities are discussed below.

a) [ ]

[

]. *Compare* CX-2068C.9 (Medytox Batch Record Version No. 5) *with* JX-0022.19 (Daewoong 450DC-010 Batch Record). [

].

[

]. *See* JX-0029C.216 (Min Notebook); CX-0010C (Pickett WS) at Q/A 313; CX-2068C.27 (Meditoxin Batch Record). [

]. RDX.0002C.6 (Wilson WS Demonstrative Ex.). [

]. *See* RX-

3164C (Wilson WS) at Q/A 138; RX-3161C (CS Kim WS) at Q/A 94. [

]. JX-0116.4, 10 (Abrams (1946)).

[

]." *Compare* JX-0030C (DWP450-REP-076), *with* JX-0031C (DWP450-REP-009), JX-0012C (DWP450-REP-033), JX-0016C (DWP450-REP-066E), *and* CX-1287C (Kang Email, 02/27/14). [

].

b) [ ]

[

]. *Compare* CX-2064C.10 (BK Lee Email Attach., 11/02/07), *with* JX-0022.64-67 (450DS-010 Batch Record); CX-0010C (Pickett WS) at Q/A 251, 253, 257; JX-0022C, JX-0017C, JX-0023C, CX-2068C, CX-2063C, CX-2064C. [

].

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].

See Wilson Tr. 543–544; CX-0010C (Pickett WS) at Q/A 301.

[

].” RX-3164C (Wilson WS) at Q/A 148. Yet, Daewoong was producing neurotoxin complex, not pure neurotoxin. CX-1826.465 (Daewoong Patent File Wrapper) (distinguishing Daewoong’s claimed invention, where the “target molecule to be purified . . . is ‘complexed botulinum toxin’” from prior art, which produces “non-complexed botulinum toxin (neurotoxin)” because “[o]ne skilled in the art would not have been motivated to use [methods for producing the purified toxin] when the target molecules are different”). Indeed, Dr. Wilson’s assertion is irreconcilable with Daewoong’s own assertion, in its patent and [

].

See CX-1727C.12 (DW U.S. Patent 9,512,418); JX-0007C.6 (BLA Section 3.2.S.2.6).

[ ] relied on the Malizio and Tse [

], RX-3164C (Wilson WS) at Q/A 148. [

]. Wilson

Tr. 543–544; CX-0010C (Pickett WS) at Q/A 301. [

],

Wilson Tr. 543–544, [

]. RX-3164C (Wilson WS) at Q/A 95; Wilson Tr. 543–44. [

]. JX-0120.1 (Tse (1982)). [

]. CX-0010C (Pickett WS) at Q/A 297 [

].

[

].

JX-0031C.28-29 (DWP450-REP-009); JX-0012C.30-31 (DWP450-REP-033).

c) [ ]

[

]. *See* JX-

0007C.6 (Daewoong BLA section 3.2.S.2.6) [

]. Daewoong claims it decided to [

] (JX-0126). [

]. The evidence illustrates other inconsistencies in Daewoong's statements regarding how it developed its manufacturing process and the scientific literature that purportedly provided Daewoong the motivation to [

]."

There is no evidence that Daewoong independently discovered that [

]. *See* JX-0007C.6 (BLA Section 3.2.S.2.6) [

]. Daewoong claims to have come up with this innovation not based on Medytox's R&D documents, but by deciding that [ ] was optimal because Daewoong [

]. *Id*. at 18. [

]. JX-0126.4 (Duff (1957)). [

]. CX-0010C (Pickett WS) at Q/A 260–63; RX-3164C (Wilson WS) at Q/A 151; CX-2524C (CS Kim Dep.) at 179. This is implausible. [

], RX-3161C (CS Kim WS) at Q/A 118, [

]. CX-0010C (Pickett WS) at Q/A 260–63.

2. Daewoong's Lack of Contemporaneous Documentation to Corroborate Independent Development

Respondents argue that they have been "substantially prejudiced" by the passage of time, in part because "documents have become unavailable." Resps. Br. at 279. Yet, it is unlikely that a major pharmaceutical company with international sales of drug products that require regulatory approval in most, if not all, of the jurisdictions in which its products are sold would not maintain its development records, including laboratory notebooks, that provide a contemporaneous record of its work. Furthermore, a long passage of time is not at issue. Daewoong claims that its isolation of a *C. botulinum* type A strain and the initiation of research to develop a commercial manufacturing process for a BoNT type A product from that strain occurred in late [ ], and disputes concerning its products are not recent.

Only a handful of lab notebooks have been produced in the course of this investigation that pertain to the development work for DWP-450. The allegations against Daewoong pertaining to its BTX strain and the manufacturing process for, *inter alia*, DWP-450 have been known to Daewoong since at least June 2017, when Medytox sued "Dr. [Byung Kook] Lee, Daewoong, Evolus, and numerous current and former Daewoong employees in the Superior Court of California." Resps. Br. at 12. The lack of contemporaneous research and development records, especially in the [ ] period, is highly unusual for a pharmaceutical company, especially when the drug is successfully brought to market. *See* Wilson Tr. at 584–585 (lack of contemporaneous records would be a "red flag" and a pharmaceutical company "would not get their

contract"). [

]. CX-0010C (Pickett WS) at Q/A 310. [

]. *Id*. [

]. RX-3161C (CS Kim WS) at Q/A 129. [

]. *Id*. It does not appear that Daewoong produced laboratory notebooks reflecting contemporaneous memorialization of this important development work.

Furthermore, there is a lack of any contemporaneous documentation of citations to the disparate published scientific literature dating back to as early as the 1940s on which Daewoong purportedly relied to piece together the steps of the manufacturing process for the DWP-450 drug substance. Rather, Daewoong relies on reports assembled [

]." *Id*. at Q/A 120–28. However, it does not appear that Daewoong produced laboratory notebooks reflecting contemporaneous memorialization of the work done to be summarized into such reports.

Daewoong has not provided sufficient evidence demonstrating its own independent development of its manufacturing process in order to support its arguments, and to respond to discovery requests. This should have been an easy task for Daewoong. *See Railway Wheels*, Unreviewed ID at 40 ("[A]s Amsted's expert Dr. Conley testified, TianRui should have been able to produce numerous examples of testing or development data produced if TianRui it had independently developed its cast steel railway wheel manufacturing process.").

Daewoong argues that it produced the lab notebooks of the DWP-450 team in this investigation. [

]. CX-0010C (Pickett WS) at Q/A 269. These lab notebooks do not demonstrate independent development of the drug substance. Daewoong cannot argue the deficiency in its records should be attributed to the passage of time. Daewoong's document retention policy requires documents on [

]. *See* CX-1996C.29 (DW Terms of Document Management); CX-2533C (SK Kim Dep.) at 52–53.[19] In any event, Daewoong ultimately produced the lab notebooks of the DWP-450 team. Those lab notebooks do not support a claim of independent development.

The core documentation that would support any R&D process of the type Daewoong claims to have completed would be laboratory notebooks recording the R&D

[19] After Medytox initiated its suit in California in June 2017, Daewoong imposed a litigation hold. However, Daewoong lifted this hold in [ ], despite not being dismissed from the case until April 2018. CX-2533C (SK Kim Dep.) at 65–66, 73. [ ]. *Id*. at 68–69.

work. *See* CX-0010C.28 (Pickett WS) at Q/A 137, 141, 277, 310; Wilson Tr. 582–85.[20] In response, Daewoong produced a few laboratory notebooks, from which only [ ] reflect experiments relating to the development of Daewoong's manufacturing process before Daewoong manufactured its first drug substance batch at commercial scale—and two of those pages are hardly evidence of "independent development," as they discuss [ ]. CX-0010C (Pickett WS) at Q/A 310; JX-0029C.215-16 (Min Notebook). Those lab notebooks disclose just [

]. *Id.*[21]

Daewoong's laboratory notebooks do not support Daewoong's present claim that [

]. CX-0010C (Pickett WS) at Q/A 272. [

[20] All of the technical experts who accessed Medytox's or Daewoong's laboratories to perform experiments in this case produced detailed laboratory notebooks describing their work. *See, e.g.,* RX-3276C (Singh Notebook); SX-0001C (Sherman Notebook); RX-3033C (Pickett Notebook). Medytox produced 5,343 pages of laboratory notebooks describing its own R&D process. CX-1886C (Summary of Medytox R&D Docs. Produced).

[21] [

]. RX-3161C (CS Kim WS) at Q/A 83–84; RX-3164C (Wilson WS) at Q/A 139. These examples are irrelevant to the question of misappropriation, and do not explain how Daewoong developed its initial steps in the first instance.

]. *Id*. at Q/A 295; JX-0031C (DWP450-REP-009); JX-0012C (DWP450-REP-033); JX-0016C (DWP450-REP-066E); JX-0030C (DWP450-REP-076); JX-0013C (DWP450-REP-080). However, these reports do not actually explain Daewoong's process of development.

[

]. *See* JX-0031C (DWP450-REP-009) (the interim report, drafted in September 2011); JX-0012C (DWP450-REP-033) (the final report, drafted in July 2012); Wilson Tr. 551–553. [

]. CX-0010C (Pickett WS) at Q/A 282. [

]. JX-0016C (DWP450-REP-

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066E); CX-0990C.2-4 (DW Rog. Resp. No. 90) (stating creation date for DWP450-REP-066). [

], CX-0010C (Pickett WS) at Q/A 288, 295 – and Tse (1982). [

]. CX-1286C (Marmo Email, 02/23/14). [ ]. CX-1287C (Kang Email, 02/27/14). [

]. JX-0030C (DWP450-REP-076) [

]. JX-0030C.44 (DWP450-REP-076). [

].

Daewoong also has provided different, inconsistent accounts about which academic articles it relied on as the basis for its own R&D efforts. [

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]. JX-0007C.13 (BLA Section 3.2.S.2.6). [

].

In contrast to Daewoong, Medytox has produced voluminous documents demonstrating its R&D. *See* CX-1886C (Summary of Medytox R&D Docs. Produced). Moreover, the documents produced by Medytox clearly support Medytox's use of academic literature to develop its manufacturing processes. Medytox's academic literature review began with CEO Hyun Ho Jung and his near decade of work researching botulinum and reviewing (and publishing) literature related to research-scale manufacturing methods. CX-0013C (Jung WS) at Q/A 5, 12, 47–49 (citing CX-0709C (BTX purification method), CX-0710C (Culture Medium Ingredients), CX-0711C (Purification Plan), CX-0712C (Purification Procedures)). The review continued through Medytox's early R&D efforts as it devised its plans to develop a commercially viable manufacturing process. CX-0013C (Jung WS) at Q/A 58; CX-0012C (HW Kim WS) at Q/A 18-23; CX-0017C (Chang WS) at Q/A 44; CX-2138C.1 (Studies on Immunity to Toxins of *Clostridium Botulinum*); CX-0129C.7 (Handwritten Notes). Daewoong has not challenged the sufficiency of Medytox's R&D records, or disputed the fact that Medytox produced far more voluminous contemporaneous records than Daewoong despite the fact that the relevant work occurred a decade earlier.

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3. Development Period of the Daewoong Manufacturing Process

Daewoong began work on developing a manufacturing process in [ ] and produced its first batch of DWP-450 drug substance at commercial scale in [ ]. *See* JX-0026C-JX-0029C, CX-2598C, JX-0017C. The administrative law judge finds that it is not credible to reach the milestone of a commercial scale batch in such a short period of time. *See* CX-0010C (Pickett WS) at Q/A 303–16. Based on his over 40 years of experience in the industry, Dr. Pickett has estimated it would take at least three months for an inexperienced team seeking to develop a manufacturing process from scratch to review the academic literature and an additional 18 months to conduct small scale process research experimentation before proceeding to a commercial-scale batch. *Id.* at Q/A 320–25.

Chung Sei Kim, the leader of the DWP-450 project, [ ]. *See* CX-2524C (CS Kim Dep.) at 128. He was a new hire at Daewoong in [ ], and joined the DWP-450 project as team lead [ ]. *See* CX-2525C (CS Kim Dep.) at 19–20. [ ], RX-3161C (CS Kim WS) at Q/A 63, [ ]." CX-2525C (CS Kim Dep.) at 121–22; CX-2524C (CS Kim Dep.) at 177. [

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]. *See* JX-0026C.43-47 (CS Kim Notebook). This work does not appear to be process development work, but rather simply [ ].

The next member of the DWP-450 team was Kwan Young Song, [ ]. CX-1794C.44 (DW Rog. Resp. No. 26). [

]. *See* JX-0027C.213-25 (Song Notebook); CX-0010C (Pickett WS) at Q/A 309–13. [ ].

The final member of the DWP-450 team was Kyung Min Min, an intern who joined Daewoong on [ ], CX-2205C.5 (Min Personnel Card), and was regularly tied up on other projects. *See* CX-2524C (CS Kim Dep.) at 176. His lab notebook reflects [ ]. *See* JX-0026C-JX-0029C, CX-2598C, JX-0017C; JX-0029C (Min Notebook). [ ]. JX-0029C.204-210 (Min Notebook). [ ]. JX-

0029C.215-16 (Min Notebook). [

]. JX-0029C.220-23 (Min Notebook).

[

]. JX-0029C.227 (Min Notebook). [

]. JX-0029C.230-231 (Min Notebook).

[

] does not detract from the obvious head start Daewoong exploited to reach this milestone so rapidly.

[

]. RX-3163C (Singh WS) as Q/A 21.

[

]. CX-2524C (CS Kim

Dep.) at 234. [

]. CX-1832.60 (Decision in Korean Criminal Case); CS Kim Tr. 683–685. [

]. *See* JX-0017C (Culture Records for DWP450 DS-001-006); JX-0018C (Culture Records for DWP450DS-011-015); JX-0023C (Culture Records for DWP450 DS-002, -007-010).

[

]. *See* JX-0012C.31 (DWP450-REP-033); JX-0031C (DWP450-REP-009); Wilson Tr. 551

[

]. CX-0818C.3 (DWP450-REP-037); CX-0010C (Pickett WS) at Q/A 283.

The record establishes that Daewoong achieved the operation of its manufacturing process at commercial scale by early [

]. From a practical standpoint, such a schedule could not be achieved through independent development from scratch. This is particularly the case in

view of team's lack of BTX experience, the purported development work was done by an intern, and the minimal amount of actual development activity recorded in that time span.

The administrative law judge finds that Daewoong wrongfully took the trade secrets by unfair means. *See Rubber Resins*, Comm'n Op. at 10 (*citing Sausage Casings*, ID at 361).

VIII. Domestic Industry

A. Whether Allergan's Investments in BOTOX® Can Satisfy the Domestic Industry

Complainants argue, in part:

> Respondents argue—as they did with regard to Allergan's standing—that Allergan's domestic industry investments should not be credited because Allergan does not "own" the trade secrets at issue. This argument is meritless. In a non-statutory IP case such as this, the domestic industry need not relate to the trade secrets, provided that the misappropriation of the relevant trade secrets threatens injury to Complainants' domestic industry. In *TianRui*, the Federal Circuit rejected the argument "that in trade secret cases, the domestic industry must practice the misappropriated trade secret in order for the Commission to be authorized to grant relief." *TianRui*, 661 F.3d at 1335-37. The court held that it was appropriate to consider an industry in domestically produced products that "directly compete" with the imported products—as is the case here. *Id.* at 1337; *see also Rubber Resins ID* at 648–51.
>
> Likewise, and as the statute makes clear, Complainants need to show only that there is "an industry in the United States," *not* an industry of the trade secret owner. 19 U.S.C. § 1337(a)(1)(A)(i). Indeed, the Commission has repeatedly held that the activities of complainants who lack legal title in the intellectual property at issue can be "relevant in establishing a domestic industry" because Section 337 "does not specify which corporate entity must demonstrate investments in that domestic industry." *Certain Prod. Containing Interactive Program Guide & Parental Control Tech.*, Inv. No. 337-TA-845, Initial Determination at 275–79, 2013 WL 3463385, at *171–73 (June 7, 2013) (finding

that entities who did not own the intellectual property at issue had standing to be complainants and crediting their investments to find that a domestic industry existed); *see also Certain Optical Disc Drives*, Inv. No. 337-TA-897, Corrected Comm'n Remand Order at 4 (Sept. 29, 2014) (holding that Section 337 requires only that an industry in the United States shall be considered *to exist*, "but does not specify that such industry must be comprised of one particular entity").

Further, the Commission's rules expressly provide that entities that do not own the intellectual property at issue may join as co-complainants and that a complainant IP owner may satisfy the domestic industry requirement through the domestic operations of its licensees. *See* 19 C.F.R. § 210.12(a)(7) ("For every intellectual property based complaint (regardless of the type of intellectual property right involved), include a showing that ***at least one*** complainant is the owner or exclusive licensee of the subject intellectual property") (emphasis added); 19 C.F.R. § 210.12(a)(6)(ii) ("include a detailed description of the domestic industry affected, ***including the relevant operations of any licensees***") (emphasis added).

Here, Allergan is both a co-complainant and an exclusive licensee of Medytox, the owner of the trade secrets asserted in this case. *See supra* Section I.C.2. Accordingly, a domestic industry may be established through the domestic operations of Allergan, even though it is not the IP owner. *See also Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Order No. 22 at 7, 2006 WL 855798, at *4 (Mar. 15, 2006) ("[T]he economic prong of the domestic industry requirement can be established where a complainant bases its claim exclusively on the activities of a contractor/licensee."). To date, Respondents have cited no authority to the contrary—and Complainants are aware of none. Respondents' argument that counting Allergan's investments in the domestic industry would enable "mere importers" to rely on the investments of "unrelated parties" and "circumvent" the domestic industry requirement is not credible. Resps. Prehr'g Br. at 159 (citing *Corning Glass Works v. ITC*, 799 F.2d 1559, 1569–70 (Fed. Cir. 1986)). It cannot be squared with the undisputed facts of this Investigation. Indeed, it is undisputed that Allergan has spent billions of dollars in domestic manufacturing, quality control, research and development, and testing related to

> BOTOX®. *See infra* Section VI.B.2. Moreover, in light of its 2013 license agreement with Medytox making it the exclusive licensee of MT10109L and its significant up-front and on-going investments associated with that project, Allergan is plainly not an "unrelated" party.

Compls. Br. at 209–11 (footnote omitted).

Respondents argue, in part:

> [W]hen assessing what ought to be included within the scope of a cognizable domestic industry in an ITC trade secret case, the Commission looks to the domestic industry of the owner or exclusive licensee of the trade secrets. Indeed, in every single trade secret case resolved through determination, the alleged domestic industry has belonged to the owner or exclusive licensee of the asserted trade secrets. *See, e.g.*, *Activity Tracking Devices,* Inv. No. 337-TA-963 (Oct. 20, 2016); *Stainless Steel Products, Certain Processes for Manufacturing or Relating to Same, and Certain Products Containing Same,* Inv. No. 337-TA-933 (Mar. 26, 2018)*; Crawler Cranes,* Inv. No. 337-TA-887 (Apr. 16, 2015)*; Certain Opaque Polymers,* Inv. No. 337-TA-883 (Apr. 17, 2015)*; Rubber Resins,* Inv. No. 337-TA-849 (Feb. 26, 2014)*; DC-DC Controllers,* Inv. No. 337-TA-698 (Aug. 13, 2010); *TianRui*, 661 F.3d at 1337; *Certain Processes for the Manufacture of Skinless Sausage Casings and Resulting Product*, Inv. No. 337-TA-148/169, ID at 341-42 (July 31, 1984) (*unreviewed*, 49 Fed. Reg. 39925 (Oct. 11, 1984)) ("*Sausage Casings*"). To Respondents' knowledge, there has never been a case at the Commission like this, where the sole claimed holder of the alleged domestic industry (Allergan) does not own or license the asserted trade secrets at all. *See supra* at III.D.
>
> Complainants and Staff do not attempt to address this long line of precedent, which places Complainants' legal maneuver distinctly outside the bounds of what the Commission has permitted in its 100-year history. But to ignore these cases and consider Allergan's BOTOX® activities would effectively eliminate the domestic industry requirement as a substantial limitation on the Commission's jurisdiction. Because Medytox and Allergan share no corporate affiliation, and because their licensing relationship does not include a license to the asserted trade secrets (let alone an exclusive license), a ruling in their favor would

mean that any foreign company lacking a domestic industry could circumvent the requirement merely by entering into a straw license with an unrelated company with a domestic industry and joining that company as a Complainant. Complainants and Staff suggest that this circumvention strategy was already endorsed by the Federal Circuit in *TianRui*, because that case holds that domestic industry not "relate" in any way to the asserted trade secrets. *See, e.g.*, CPB at 144 ("*TianRui* also confirms that in a non-statutory IP case such as this, the domestic industry need not relate to the trade secrets."). This is a glaring misreading of *TianRui* and the legislative history of the 1988 Amendments.

In *TianRui*, Complainant Amsted Industries, a U.S. manufacturer of cast steel railway wheels, developed and owned two trade secret manufacturing processes. *See Cast Steel Wheels*, ID at 17 (finding that the complainant "has established that it owns the trade secrets asserted in this investigation, and that it has standing as the complainant.") The first, known as the "ABC process," Amsted developed in the United States and had used domestically in the past. Eventually, however, Amsted came to use a different process (known as the "Griffin process") for its U.S. facilities, and licensed out the ABC process for use by certain foreign manufacturers. *See TianRui,* 661 F.3d at 1324. It was this ABC process that Amsted claimed TianRui, a foreign manufacturer, had misappropriated.

The ALJ and Commission found that TianRui had violated Section 337 because it had misappropriated the ABC process, even though, by that point, Amsted had discontinued its use of the ABC process domestically. The Federal Circuit agreed with the Commission that Amsted's ability to secure relief was not contingent upon it actually using the misappropriated trade secrets domestically during the investigation. *See TianRui*, 661 F.3d at 1335-37. In other words, the central holding of *TianRui* was that a complainant's domestic industry need not currently ***practice*** the asserted trade secrets. *Id*. at 1337.

It was never in doubt, however, that Amsted was *both* the party whose domestic industry was injured *and* the party that owned that misappropriated ABC process. The Federal Circuit expressly relied upon this fact in its holding: "The parties submitted evidence indicating that the imported TianRui wheels could directly compete with wheels

domestically produced ***by the trade secret owner***." *Id*. at 1337 (emphasis added). In the Court's view, even if the domestic industry holder were no longer *practicing* the trade secrets, the Commission should be able to remedy foreign misappropriation of those trade secrets that worked "to the detriment of ***the trade secret owner***." *Id*. at 1330 (emphasis added).

In other words, *TianRui* is in keeping with the traditional notion that a U.S. company's development of trade secrets can and should be protected. Nothing in *TianRui* permits Allergan to assert the misappropriation of another company's trade secrets that it does not own, have an exclusive license to, or even have *access* to. That would reward Allergan with the prospect of an exclusion order to protect asserted trade secrets that it did not develop, has no rights to, has never seen and never used; and to remedy alleged wrongful conduct that it never experienced. It would also allow Medytox, a company that lacks any domestic industry of its own, to litigate the alleged misappropriation of foreign trade secrets that have never been owned or licensed to any U.S. entity. This cannot be the rule.

The only investigation Respondents have identified with even remotely similar facts to those presented here is *Sausage Casings*, which held that an alleged licensee's domestic activities and investments were not relevant to the domestic industry inquiry. In *Sausage Casings*, co-complainants Union Carbide and Teepak brought consolidated patent- and trade secret-based investigations relating to the manufacturing processes for sausages. Complainants sought to establish a domestic industry through the manufacturing investments of the trade secret owner, Union Carbide, as well as its alleged licensee, Teepak. The ALJ refused to consider Teepak's alleged domestic industry, holding:

> The record reveals that although the 1967 Agreement between Teepak and Union Carbide included provision for exchange of know-how, that the know-how exchange was never fully carried out, and that Teepak essentially did not use the know-how received from Union Carbide. (Findings of Fact 533-538, 549). There is nothing on the record to indicate that any other domestic

> company is making use of the trade secrets at issue. Thus, for purposes of the trade secret phase of this investigation, the domestic industry is defined to include only the domestic operations of Union Carbide's Films-Packaging Division utilizing the trade secrets at issue.

Sausage Casings, ID at 341-42. The Commission adopted the ALJ's findings.

For the same reasons and more, the ALJ should reject Allergan's alleged domestic industry activities and investments. Here, although the 2013 Agreement between Medytox and Allergan governing MT10109L includes a provision for the exchange of "[ ]," that [ ] relates to alleged trade secrets that are *unasserted* here — *i.e.*, trade secrets related to MT10109L, *not* Meditoxin®. JX-0050C.14-15, 20 (Allergan-Medytox License Agreement); RX-3014C.12, 17 (Neervannan Dep. Desg. 46:5-9, 66:24-25). Thus, unlike Teepak, Allergan is not even a licensee to the asserted trade secrets. Moreover, although there is no "technical prong" element required under Section 337(a)(1)(A), it was important in *Sausage Casings* that Teepak, like Allergan here, never received or used the alleged trade secrets. Accordingly, as in *Sausage Casings* and *TianRui*, the domestic industry is — and can only be — the alleged domestic industry of the trade secret owner or exclusive licensee.

Resps. Br. at 228–31 (footnote omitted).

The Staff argues, in part:

> Respondents argue that Complainants cannot establish a domestic industry based on the flawed premise that Allergan lacks standing as a complainant in this Investigation. For at least the reasons discussed in section II.D of the Staff's initial posthearing brief and section II.B, *supra*, Respondents' argument that Allergan lacks standing and, thus, Allergan's investments relating to BOTOX and MT10109L should not be considered, is flawed.

Staff Reply Br. at 31.

In *TianRui*, the Federal Circuit rejected the argument that in trade secret cases, the domestic industry must practice the misappropriated trade secret in order for the Commission to be authorized to grant relief. *TianRui*, 661 F.3d at 1335–37. The court held that it was appropriate to consider an industry in domestically produced products that "directly compete" with the imported products. *Id.* at 1337; *Rubber Resins*, ID at 648–51.

Under Commission precedent, a complainant may rely upon investments by unrelated licensees to prove the existence of a domestic industry requirement. *See, e.g., Certain Electronic Imaging Devices*, Inv. No. 337-TA-726, Order No. 18, at 8–19 (Feb. 7, 2011) (granting summary determination that complainant satisfied the domestic industry requirement based on licensees' investments), *aff'd*, Notice of Commission Determination Not to Review an Initial Determination Granting Complainant's Motion for Summary Determination That It Satisfies the Economic Prong of the Domestic Industry (Mar. 8, 2011).[22]

In the case at hand, Allergan is both a co-complainant and an exclusive licensee of Medytox, the owner of the trade secrets asserted in this case. Accordingly, a domestic industry may be established through the domestic operations of Allergan, even though it is not the IP owner. *See Certain Methods of Making Carbonated Candy Products*, Inv. No. 337-TA-292, ID at 142, (U.S.I.T.C. December 8, 1989) (unreviewed in relevant part)

[22] In *TianRui*, the Federal Circuit affirmed the Commission's domestic industry analysis in *Railway Wheels*. 661 F.3d at 1337. Notably, in *Railway Wheels*, the complainant Amsted was the sole owner of the trade secrets at issue in the case. *Railway Wheels*, Unreviewed ID at 12–17. The domestic industry requirement was satisfied based on the investments of Amsted's subsidiary Griffin Wheels, which neither practiced nor owned the misappropriated trade secrets at issue. *See id.* at 80–81.

(finding existence of a domestic industry based on long-term, completely domestic production of candy by a contractor/licensee utilizing the patented process).

B. Allergan's Domestic Industry

Complainants argue, in part:

> The proper scope of the domestic industry includes all of the Domestic Industry Products—BOTOX® Cosmetic, BOTOX® therapeutic, and MT10109L. "It is well settled that the scope of a section 337 investigation is determined by the Notice of Investigation issued and published by the Commission." *Rubber Resins ID* at 619. In this case, the Notice of Investigation defines the scope of the investigation in terms of "botulinum neurotoxin products." *Certain Botulinum Toxin Prod.*, Inv. No. 337-TA-1145, Notice of Institution of Investigation at 2 (Feb. 28, 2019). Accordingly, the relevant domestic industry here includes Complainants' domestic activities relating to "botulinum neurotoxin products," i.e., BOTOX® Cosmetic, BOTOX® therapeutic, and MT10109L.

Compls. Br. at 208.

Respondents argue, in part:

> But should the Commission consider BOTOX® investments as part of the domestic industry analysis, notwithstanding these defects, Complainants still have not met their burden to prove a relevant domestic industry. Complainants' various allocations of purported U.S-based investments in BOTOX®, even if credited, do not establish a domestic industry that is substantial when compared to Allergan's worldwide BOTOX® operation. *See, e.g.*, *Carburetors*, Comm'n Op. at 18-26 (conducting a contextual analysis of domestic industry to conclude that complainant's investments were insubstantial in context). Indeed, as a threshold issue, every unit of BOTOX® sold in the United States is first imported from Allergan's Westport, Ireland manufacturing facility. RX-3158C.22 (Mulhern WS) at Q/A 114; JX-0037.27 (Allergan, Form 10-K, 2018). Mr. Malackowski's failure to sufficiently compare Allergan's alleged U.S. investments to Allergan's substantial investments at its Ireland location — where, according to Allergan's own securities filings, BOTOX® manufacturing

> "***is exclusively performed,***" JX-0037.27 (Allergan, Form 10-K, 2018) (emphasis added) — dooms his analysis. Moreover, Complainants have relied on transparently hollow "evidence" to show substantiality in context, such as an Allergan executive's back-of-the-envelope estimate of where BOTOX® derives its value, divorced from any quantitative analysis or documentary support. RX-3158C.22 (Mulhern WS) at Q/A 111-112; CX-0016C.7 (Neervannan WS) at Q/A 22. With respect to the claimed U.S. investments themselves, Mr. Malackowski's analysis suffers from numerous shortcomings, including double counting, including unquantified domestic activity from decades ago, and the comingling of activities aimed at non-domestic industry products. RX-3158C.23, 25 (Mulhern WS) at Q/A 123, 130-134. For all these reasons, Complainants have failed to prove a relevant domestic industry even if BOTOX® investments are deemed legally relevant.

Resps. Br. at 236–37.

The Staff argues, in part:

> Complainants assert that Allergan has a domestic industry in 900 kDa botulinum toxin products, including BOTOX® Cosmetic, BOTOX therapeutic, and MT10109L (collectively, "the DI Products"). "It is black letter law that the scope of a Section 337 investigation is determined by the Commission's Notice of Investigation ('NOI')." *Certain Consumer Electronics & Display Devices with Graphics Processing & Graphics Processing Units Therein*, Inv. No. 337-TA-932 ("*GPUs*"), ID at 4 (Oct. 9, 2015) (EDIS Doc. No. 568758).

Staff Br. at 121.

In this case, the notice of investigation defines the scope of the investigation in terms of "botulinum neurotoxin products." 84 Fed. Reg. 8112 (Mar. 6, 2019). Accordingly, the relevant domestic industry includes BOTOX® Cosmetic, BOTOX® therapeutic, and MT10109L.

PUBLIC VERSION

1. Allergan's Investments Relating to BOTOX®

Complainants argue, in part:

> Over the past 30 years since BOTOX® was first approved by FDA, Allergan has continuously invested billions of dollars in domestic manufacturing, R&D, labor and capital, and sales and marketing activities essential for the commercialization of BOTOX®. Complainants' economic expert Mr. Malackowski opined that Allergan created the U.S. market for BTX products and expanded the potential uses of such BTX products, which has benefitted follow-on market entrants like Respondents. CX-0018C at Q/A 44-51. As a result of its substantial investments, Allergan today sells millions of vials of BOTOX® in the United States yearly—with approximately [ ] of the vials being BOTOX® Cosmetic—resulting in over [ ] in U.S. sales revenue each year. CX-0018C at Q/A 46-47; CX-0008C (Marzouk WS) at Q/A 10, 12-17; CX-2323C (tab "Botox C P&L from BPC"); CX-2322C (tab "Botox Tx P&L from BPC"); CX-2251C (Units of BOTOX® Manufactured for 2014 to 2018); CX-2254C (Allergan gross and net sales for BOTOX®); CX-2253C (Allergan revenue model for BOTOX®); JX-0072, JX-0035, JX-0036, and JX-0037 (Allergan SEC 10-Ks for 2014 to 2018, respectively). The units of BOTOX® sold every year and the revenue they generate "provide[] evidence that the domestic industry is substantial." *Rubber Resins ID* at 623; *Railway Wheels ID* at 81 (considering annual sales to find that the domestic industry is substantial.

Compls. Br. at 211–12.

Respondents argue, in part:

> Creating a market for a product has never formed the basis of a domestic industry and it should not now. Even if it could, a large portion of the proffered investments (which Complainants have not quantified) are too old to warrant consideration. The claimed investments in this category relate to research and development for BOTOX® products made as early as ***1989 – i.e., over two decades ago***. CX-0018C.13 (Malackowski WS) at Q/A 44. As much as [ ] these investments were made during a time period (1989 through 2000) in which Medytox and its alleged trade secrets *did not even exist*. Compl. ¶ 18. At a minimum,

> Complainants should not be permitted to rely upon Allergan's investments made prior to its 2013 License Agreement with Medytox.
>
> In addition, Mr. Malackowski does not delineate the type of investments that purportedly make up this category, instead branding the investments considered as "investments related to [Allergan's] efforts to secure FDA approval" for BOTOX®. CX-0018C.13 (Malackowski WS) at Q/A 45. But he does not actually quantify the "FDA approval" investments upon which he purportedly relies. CX-0018C.13-17 (Malackowski WS) at Q/A 45.
>
> Complainants' calculation is further laden with improper double-counting. For instance, Complainants attempt to claim investments in R&D for BOTOX® Therapeutic and Cosmetic as evidence of "investments in creating the market for BTX products," and then re-count those same investments again when describing a purportedly separate category of spending entitled "investment in research and development of BOTOX®." RX-3158C.20-21 (Mulhern WS) at Q/A 104-05.

Resps. Br. at 240–41.

The administrative law judge finds that Allergan has invested billions of dollars in the United States for manufacturing, R&D, commercialization, and sales and marketing activities to create and expand the U.S. BTX market. CX-0018C (Malackowski WS) at Q/A 21. As a result of these efforts and investments, Allergan has received FDA approval for more indications than all of the other BTX products in the U.S. market combined. *Id*. at Q/A 44, 45, 49; CX-2343C (Allergan Corporate Overview); CX-2335C (Pediatric Spasticity Advisory Board Presentation); CX-2343C; CX-1197, CX-1198; CX-1200, CX-1201, CX-1202, CX-1203, CX-1204, CX-1205, CX-1206, CX-1209. Allergan's research continues in planning for a number of new indications across unique specialties. CX-0018C at Q/A 45, 49; CX-2342C (Neurotoxin Strategy).

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The manufacturing process of [ ] of BOTOX® sold worldwide begins with the production of the active pharmaceutical ingredient ("API") (also called the "drug substance") at a secure manufacturing facility located in [ ]. *See* CX-0016C (Neervannan WS) at Q/A 20; CX-0008C (Marzouk WS) at Q/A 9; CX-0018C at Q/A 52. Dr. Neervannan testified that the production of the API entails a series of complex and sophisticated processes, including the cultivation of *C. Botulinum* bacteria from a proprietary cell bank and isolation and purification of the botulinum neurotoxin. CX-0016C at Q/A 21.

The API is the most valuable and most important component to the BOTOX® product. CX-0018C at Q/A 54; CX-0016C at Q/A 22. The API causes the pharmacological and clinical action that BOTOX® delivers. CX-0016C at Q/A 22. Dr. Neervannan estimated the value of the API constitutes at least [ ]. *Id*. at Q/A 22. Once the BOTOX® API has been manufactured, it is delivered to Allergan's "finish and fill" facility in Westport, Ireland, which [ ]. *See* CX-0016C at Q/A 20; CX-0008C at Q/A 73; CX-0018C at Q/A 53. The finished vials of BOTOX® are then [ ]. *Id*.

Furthermore, Allergan continues to invest [ ] in R&D in the United States to improve its manufacturing process, develop additional therapeutic and cosmetic indications for BOTOX®, and comply with FDA regulatory requirements, including conducting clinical testing necessary to secure additional approvals from the FDA. *Id*. Allergan makes substantial investments in domestic sales and marketing activities, CX-

0008C at Q/A 9, 65, including in extensive physician education activities, CX-0009C (McKenna WS) at Q/A 44.

Respondents argue, in part:

> Complainants do not identify, explain, or quantify Allergan's manufacturing-related investments in the United States, much less prove that such investments are substantial or significant compared to its foreign BOTOX® manufacturing investments. RX-3158C.21-22 (Mulhern WS) at Q/A 107, 111; CX-0016C.7 (Neervannan WS) at Q/A 22. This is a fatal flaw. *See, e.g., Interdigital Commc'ns*, 707 F.3d at 1300; *Certain Ultra-Microtome Freezing Attachments*, 337-TA-10, Comm'n Op. at 8-9 (Apr. 2, 1976). Mr. Malackowski relies exclusively on Allergan's investment in a domestic facility allegedly used to produce the API for both BOTOX® Therapeutic and Cosmetic. CX-0018C.18 (Malackowski WS) at Q/A 55. But Complainants refused to produce relevant documents relating to such manufacture and so cannot rely upon it now. Order No. 24 at 2-3. Mr. Malackowski also does not account for the fact that [ ], and that is for manufacturing only a portion of the ultimate BOTOX® product. CX-18C.18 (Malackowski WS) at Q/A 55; RX-3158C.21 (Mulhern WS) at Q/A 108; CX-0016.7 (Neervannan WS) at Q/A 24.
>
> Additionally, Complainants fail to allocate out activities and investments relating to the manufacturing of BOTOX® API for BOTOX® sold abroad, which cannot contribute to the domestic industry analysis. *See* RX-3158C.21 (Mulhern WS) at 107. Complainants have not carried their burden of reliably allocating investments to BOTOX®. *See Certain Dimmable Compact Fluorescent Lamps and Products Containing Same*, Inv. No. 337-TA-830, ID at 63-64 (Feb. 27, 2013) (refusing to give weight to investments that included non-domestic industry products and stating that "what [complainant] is really asking me and the Commission to do is speculate").

Resps. Br. at 241–42.

Complainants argue, in part:

> Respondents make unsubstantiated arguments

> concerning Allergan's investments – for example, that Allergan must make an "apples-to-apples analysis of investments in the U.S. versus abroad." RIB at 238. No such requirement exists. CIB at 228-29. In any event, Complainants provided a quantitative and qualitative comparative analysis showing the significance of Allergan's domestic investments. *Id.* at 229-31; CX-0018C (Malackowski WS) at Q/A 107-08.
>
> Respondents also criticize Mr. Malackowski's analysis and conclusion that the domestically manufactured API contributes [ ] (RIB at 239-40) – yet they elected not to question either Mr. Malackowski or Dr. Neervannan (who provided the [ ] based on his decades of experience) about the basis of this valuation during the Hearing.

Compls. Reply Br. at 37–38 (footnote omitted).

The Staff argues, in part:

> Respondents also argue that Allergan's domestic investments related to BOTOX have not been shown to be substantial in context. RIB at 237. It is not disputed that the active pharmaceutical ingredient—*i.e.*, the botulinum toxin type A1 complex—is manufactured entirely in the United States. CX-0016C (Neervannan WS) at ¶ 21. Dr. Neervannan, who is Allergan's senior vice president of pharmaceutical development, testified that the active pharmaceutical ingredient (API) for BOTOX is [ ]. *Id.* at ¶ 22. Respondents argue this Dr. Neervannan's testimony is rebutted by Allergan documents that show [ ]. RIB at 240, citing RX-2442C.39. Respondents' equating [ ] to the product is fundamentally flawed. The notion that the API of a pharmaceutical product is anything less than the most important and essential aspect of the pharmaceutical product, in the Staff's view, ignores the very basic realities of pharmaceutical production.

Staff Reply Br. at 31.

Viewed in context, the evidence demonstrates that the BOTOX®-related operations Allergan conducts in Westport, Ireland do not diminish Allergan's significant

and substantial investments in the domestic industry. CX-0018C at Q/A 107–08. Mr. Malackowski testified, even considering Allergan's investments in Westport, Allergan has made an enormous historical investment in BOTOX® in the United States, including to create a domestic industry for BTX products (which continues to this day). *Id*.

As an initial matter the "finish and fill" processes at Westport, Ireland [

].

See CX-0018C at Q/A 108; CX-0016C at Q/A 20. Dr. Neervannan testified that the domestically-manufactured API accounts for [

]. CX-0016C at Q/A 22. This evidence shows that critical operations such as the manufacturing of the API, physician support activities, and nearly all of the R&D activities all occur in the United States. Thus, Allergan's domestic operations are qualitatively significant in comparison to its foreign operations.

Moreover, the labor expenses for BOTOX® incurred at Westport [

]. Allergan's direct labor expenses for BOTOX® at Westport were [ ] in 2017 and [ ] in 2016. *See* CX-0008C at Q/A 77; CX-0018C at Q/A 108; CX-2315C (Westport BOTOX® Spend). By contrast, Allergan's annual domestic labor expenses for just its full-time employees who work on BOTOX® (excluding the vast majority of its R&D personnel) is more than [ ].

Although the overhead expenses at the Westport facility [

]. CX-0008C at Q/A 74; CX-0018C at Q/A 108.

The acquisition value of the BOTOX®-related assets at Westport was approximately [ ], capitalized from 2001 to 2019, with a current book value of approximately [ ] as of June 30, 2019. CX-0008C at Q/A 75-76; CX-2345C and CX-2347C (Fixed Asset Register for BOTOX®). This is only a fraction of Allergan's investments in domestic research and development from 1992 to Q1 2019, domestic plant and equipment, and just one years' worth of domestic employee salaries exceed [ ].

In view of the differing nature of the activities performed in Ireland and the United States, and the large differential in the investments made by Allergan in those two countries, the administrative law judge finds that Allergan's operations in Ireland do not diminish Allergan's significant and substantial investments in the domestic industry. *See Certain Carburetors and Prods. Containing Such Carburetors*, Inv. No. 337-TA-1123, Comm'n Op. at 18–20 (Oct. 28, 2019).

a) Allergan's Investments in Domestic Plant and Equipment Relating to BOTOX®

Complainants argue, in part:

> The undisputed evidence has established that Allergan has acquired over [ ] square feet and invested nearly [ ] in domestic facilities supporting the ongoing commercial manufacture, research, development, and commercialization of BOTOX®, including more than [ ] in fixed assets. Mr. Malackowski testified that Allergan's investments are both significant and substantial, in absolute terms and relative to the domestic activities of another BTX manufacturer, and demonstrate that Allergan has a domestic industry in BOTOX®. CX-0018C at Q/A 26, 63, 65, 68, 78, 80, 106. *See also Rubber Resins ID* at 694 (crediting expenses invested in manufacturing facility from 1968 through 2011 to find that a domestic industry existed); *Railway Wheels ID* at 9, 80–81 (crediting current book value of three facilities acquired from 1958 to 1986 used in

> manufacturing and R&D to find that a domestic industry existed.

Compls. Br. at 219.

Respondents argue, in part:

> Complainants claim Allergan investments in [ ] as part of their alleged domestic industry investments in BOTOX®. CX-0018C.21 (Malackowski WS) at Q/A 64. [ ]. CX-2571C.58-59 (Allergan Third Responses to Staff Interrogatories) at No. 5. None of them utilize or have any nexus whatsoever to the alleged trade secrets. [ ], the [ ] facility, allegedly relates to the manufacture of BOTOX® API before it is [ ] for further production and then [ ] into the United States for sale. *Id*. at 13 (No. 4). Although Complainants claim the [ ] facility as a cognizable domestic industry investment, they have acknowledged that [ ]. CX-0016.7 (Neervannan WS) at Q/A 24; CX-2571C.8 (Allergan Third Responses to Staff Interrogatories) at No. 1.
>
> The allegations relating to the [ ] also are unsupported and lack credibility. Complainants again rely heavily on unsupported witness testimony for allegations of square footages and functions of these facilities. CX-0018C.21 (Malackowski WS) at Q/A 64.
>
> Complainants fail to exclude from their analysis investments relating to foreign indications of BOTOX®, which are not relevant to the domestic industry analysis. RX-3158C.24 (Mulhern WS) at Q/A 126. In addition, Mr. Malackowski admits that [ ]. CX-0018C.21 (Malackowski WS) at Q/A 64; RX-3158C.24 (Mulhern WS) at Q/A 125. Such non-manufacturing activities are typically performed by a mere importer and are not relevant to the domestic industry inquiry. RX-3158C.24 (Mulhern WS) at Q/A 124.

Resps. Br. at 242–43.

The Staff argues, in part:

> Allergan owns and operates multiple buildings [ ], where manufacturing, quality control, research and development, and testing activities related to BOTOX occur. CX-0008C (Marzouk WS) at ¶¶ 9, 19; CX-0016C (Neervannan WS) at ¶¶ 34-35; CX-0018C (Malackowski WS) at ¶¶ 52, 55, 64; CDX-7[ ].

Staff Br. at 123.

The evidence shows that Allergan owns and operates multiple buildings [ ] where manufacturing, quality control, research and development, testing, and sales and marketing activities related to BOTOX® occur, for which Allergan has invested more than [ ].[23] *See* CX-0008C at Q/A 9, 19, 20; CX-0016C at Q/A 34–35; CX-0018C at Q/A 52, 55, 64, 76; CX-1041C, CX-1065C. These include the following:

[ ]. Allergan owns and operates [ ], an [ ] square foot facility located [ ], where [ ]. *See* CX-0008C at Q/A 19; CX-0016C at Q/A 24; CX-0018C at Q/A 52, 55, 64. [ ] has granted Allergan a drug manufacturing license for this facility. CX-1175C (Drug Manufacturing License for [ ]); CX-0018C at Q/A 52. [ ]. CX-0016C at Q/A 23; CX-0018C at Q/A 52.

Allergan has invested [ ] in recent years to acquire specialized equipment used at [ ] for BOTOX®-related activities. CX-0008C at Q/A 21-25; CX-

[23] This total comprises approximately [ ] for facilities in [ ], which are comprehensive figures including acquisition costs, equipment, and other capital improvement projects. CX-0008C at Q/A 20.

0018C at Q/A 55, 66–67. These assets were capitalized from 2015 to 2019 and have a current book value of [ ]. CX-0008C at Q/A 21-25; CX-0018C at Q/A 55; CX-2346C (Fixed Asset Register);[24] CX-1171C [ ]. Among the specialized equipment used at [ ] for the [

]. CX-0008C at Q/A 25; CX-2346C (Fixed Asset Register).

Allergan's investments in [ ] are much more than what is typically required of a pharmaceutical production facility. CX-0016C at Q/A 25–31. Because of the highly potent and potentially lethal nature of the *C. botulinum* bacterium from which BOTOX®'s toxin is cultivated, [ ] has to comply with regulations and oversight by various government entities, including the Centers for Disease Control ("CDC"), FDA, FBI and Department of Homeland Security. *Id*. at Q/A 25, 26; CX-0018C at Q/A 57–59. Accordingly, Allergan has to ensure that [ ] has specialized equipment, operating systems, and security systems in order to comply with stringent security, safety, and health regulations when [ ], including the FDA's Good Manufacturing Processes "GMP" regulations. CX-0016C at Q/A 25, 27, 28. This has included building cleanrooms and changing rooms for [ ] personnel, as well as installing purified water and injection distillation systems, customized HVAC and filtration systems, sterilization processes and sterilization equipment, and enhanced security systems. *Id*. Allergan continually upgrades and updates its equipment and

[24] CX-2346C is a fixed asset register, which details the fixed assets Allergan owns that are used specifically to support BOTOX®-related activities at [ ]. CX-0008C at Q/A 21. Mr. Marzouk explained how to distinguish the investments at [ ]. *Id*. at Q/A 23–25.

processes as GMP standards continue to become more stringent. *Id.* at Q/A 29. Allergan's [ ] employees must also undergo substantial training and security clearance processes. *Id.* at Q/A 31.

[ ]. Allergan owns and operates multiple buildings in [ ], with more than [ ] square feet where R&D, marketing, testing, or quality control related to BOTOX® occurs (the [ ]), as described below. At least [ ] of the total space of the [ ] (approx. [ ] sq. ft.) is used for BOTOX®-related activities. CX-0016C at Q/A 36.

Facility Name	**Address**	**Sq. Footage**	**Principal Use**
[ ]	[ ]	[ ]	R&D, drafting of protocols, monitoring and statistical analysis, and overseeing clinical trials for BOTOX®
[ ]	[ ]	[ ]	R&D, and testing, including clinical studies for additional indications for BOTOX®
[ ]	[ ]	[ ]	Toxin research relating to BOTOX®, development, and testing
[ ]	[ ]	[ ]	Clinical operations and quality control testing. [ ].

On the [ ], Allergan concentrates most BOTOX®-related work at [ ], with approximately [ ] being dedicated to BOTOX®. CX-0016C at Q/A 36. The R&D work at [ ] includes (i)

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[

]. *Id*. at Q/A 35; CX-0018C at Q/A 64.

Allergan invested [ ] in recent years to acquire BOTOX®-related plant and equipment used at [ ]. CX-0008C at Q/A 21-25; CX-0018C at Q/A 66–67. These assets were capitalized from 2015 to 2019 and have a current book value of [ ]. CX-0008C at Q/A 21–25; CX-0018C at Q/A 67; CX-2346C; CX-1171C. These investments include, for example, [

]. CX-0008C at Q/A 25; CX-2346C.

Allergan has acquired over [ ] square feet and invested nearly [ ] in domestic facilities supporting the ongoing commercial manufacture, research, development, and commercialization of BOTOX®, including more than [ ] in fixed assets.

b) Allergan's Employment of Domestic Labor and Capital Relating to BOTOX®

Complainants argue, in part:

> The unrebutted evidence shows that in 2019, Allergan employed a total of [ ] domestic full-time employees who perform work related to manufacturing, research and development, and commercialization of BOTOX® and paid them a total aggregated annual compensation (including salary, bonus, and benefits) of [ ]. CX-0008C at Q/A 26-31. Information about these employees, including their positions and annual compensation, is reflected in CX-2340C, which is a spreadsheet of employment data from [ ],

> Allergan's human resources data management system. CX-0008C at Q/A 27; CX-0018C at Q/A 71-72.

Compls. Br. at 219–20.

Respondents argue, in part:

> Allergan's evidence of investments in labor and capital is also deficient. Complainants also have not identified what fraction of the cited employees' time and salaries are allocable to BOTOX®, as opposed to other Allergan products. CX-2340C (Compensation details on Allergan employees that work at BOTOX®). And once again, Allergan relies primarily on irrelevant marketing-related expenditures: [ ] employees relied upon by Allergan are sales and marketing employees. *Id.*; *see also* RX-3158C.24 (Mulhern WS) at Q/A128; *See, e.g., Certain Digital Processors and Digital Processing Systems*, Inv. No. 337-TA-559, ID at 92-93 (May 11, 2007).

Resps. Br. at 243.

The Staff argues, in part:

> In 2019, Allergan employed a total of [ ] domestic full-time employees who perform work related to manufacturing, research and development, and commercialization of BOTOX and paid them a total aggregated annual compensation (including salary, bonus, and benefits) of [ ]. CX-0008C (Marzouk WS) at ¶¶ 26–31. Information about these employees, including their positions and annual compensation, is reflected in CX-2340C, which is a spreadsheet of employment data from [ ], Allergan's human resources data management system. CX-0008C at ¶ 27; CX-0018C (Malackowski WS) at ¶¶ 71–72. These employees work across three Allergan Divisions.

Staff Br. at 127.

The evidence demonstrates that Allergan has made significant domestic investments in the employment of labor and capital related to BOTOX® (constituting

BOTOX® Cosmetic and BOTOX® therapeutic collectively) and in BOTOX® Cosmetic individually.

There are [ ] full-time employees in the United States in the [ ] who perform BOTOX® manufacturing-related job functions, such as API manufacturing, quality control, and other technical support work for the manufacturing of BOTOX®. CX-0008C at Q/A 29; CX-0018C at Q/A 72; CX-2340C (tab "Employee Details"). The work of these employees is exclusively with BOTOX®, and their total aggregated annual compensation (including salary, bonus, and benefits) is [ ]. CX-0008C at Q/A 30; CX-2340C (tab "Employee Details").

Allergan employs [ ] full-time employees in the [ ] who include medical science liaisons, the senior vice president for the clinical development of BOTOX®, and others who work in clinical development and regulatory compliance for BOTOX®. CX-0008C at Q/A 29-30; CX-2340C (tab "Employee Details"). Their total aggregated annual compensation (including salary, bonus, and benefits) is [ ]. *See id.*; CX-0018C at Q/A 72.

Allergan employs [ ] full-time employees in the United States in the [ ] who perform job functions related to the commercialization of BOTOX®, including sales, physician education, business analytics, setting business strategy, and management of commercial operations. CX-0008C at Q/A 29-30; CX-2340C (tab "Employee Details"). Their total aggregated annual compensation (including salary, bonus, and benefits) is [ ]. *Id.* There are [ ] employees who work on BOTOX® therapeutic and do so exclusively. CX-2340C (tab "Employee Details," Function "US Botox Therapeutic"). The remaining commercial employees are part of the

dedicated BOTOX® team, but they may have responsibilities beyond just the BOTOX® brand. However, the fact that some of them may have additional responsibilities does not change or alter the number of employees and the labor required to carry out all of the BOTOX® related activities necessary for the domestic industry.

In addition to the employees discussed above, Allergan also employs a large number of R&D personnel who record their time on a project by project basis. CX-0008C at Q/A 32–35; CX-0018C at Q/A 73, 74. The number of these R&D personnel who recorded time to BOTOX® related projects was [ ] in 2014, [ ] in 2015, [ ] in 2016, [ ] in 2017, and [ ] in 2018. CX-0008C at Q/A 34; CX-2276C, CX-2277C, CX-2278C, CX-2279C, and CX-2280C (BOTOX® Actual Hours for 2014 to 2018, respectively). The cost of their labor is included in Allergan's R&D investments and reflected in CX-2350C (BOTOX® R&D Data, tabs "Internal External Description" and "US&Int Botox").

Moreover, Allergan makes capital investments at [ ]. CX-0008C at Q/A 36-47; CX-0018C at Q/A 55, 79; CX-2292C (Revised [ ] ACER Report). From 2013 through Q1 2019, capital expenditures totaling [ ]. CX-0008C at Q/A 45; CX-0018C at Q/A 78, 79; CX-2308C (Capital Expenditures Report for [ ]).

At [ ], recent capital expenditures include projects related to Allergan's plans to [ ]. CX-0008C at Q/A 40–42. Evidence describing these capital investments includes a

PowerPoint presentation dated May 2018 that further explains the background, rationale, proposal and scope of the [ ] and three related budget request forms: CX-1065C, CX-2287C, CX-2289C, CX-2291C. Evidence describing some of the capital expenditures occurring at [ ] includes three budget reports: CX-2286C, CX-2288C, and CX-2290C. Allergan recently invested approximately [ ]. CX-0016C (Neervannan WS) at Q/A 30.

Mr. Malackowski opined that Allergan has employed significant and substantial labor domestically related to BOTOX® and made significant capital expenditures related to BOTOX®, which each demonstrate that Allergan has a domestic industry in BOTOX®. CX-0018C at Q/A 26, 69, 70, 75, 78, 80, 81, 106. *See Railway Wheels*, Unreviewed ID at 80–81 (U.S. employees working on the manufacture and R&D of domestic industry products supported existence of domestic industry in a trade secret case).

c) Allergan's Domestic Research and Development Investments Relating to BOTOX®

Complainants argue, in part:

> The unrebutted evidence shows that from 1992 through Q1 2019, Allergan invested [ ] in research and development related to BOTOX®, of which [ ] was invested domestically. CX-0008C at Q/A 48-54; CX-0018C at Q/A 83; CX-2327C (BOTOX® R&D Data, tab "US&Int Botox"); CX-2350C (BOTOX® R&D Data, tab "US&Int Botox"). This includes R&D related to improving Allergan's manufacturing process, expanding the number of cosmetic and therapeutic indications approved by the FDA, and complying with FDA regulatory requirements, including clinical testing required by the FDA. CX-0016C at Q/A 10, 18-19, 32, 33, 35; CDX-0009 (BOTOX® Domestic R&D Investment Expenses) (CX-2350C, CX-2327C, CX-2385C); CX-1042 (process of FDA approval process).

. . .

All costs directly associated with or allocated to research and development are included in these investments. CX-0008C at Q/A 53. Specifically, these R&D investments include [

]. CX-0008C at Q/A 53; CX-0018C at Q/A 85; CX-2350C (BOTOX® R&D Data, tab "Internal External Description"). Both internally allocated costs and external costs, including those costs related to obtaining FDA approval, may be credited to establish a domestic industry. *See, e.g.*, *Certain Solid State Storage Drives*, Inv. No. 337-TA-1097, Comm'n Op. at 22–24, 2018 WL 4300500, at *14 (June 29, 2018) (holding that payments for services rendered by independent contractors or subcontractors may be credited in establishing the existence of a domestic industry); *see also* CX-0018C at Q/A 86.

Looked at in terms of hours, Mr. Malackowski testified that between 2014 and 2018 alone, Allergan's R&D employees spent over [ ] aggregated research hours in the United States working on BOTOX®-related R&D projects. CX-0018C at Q/A 88; *see also* CX-2276C, CX-2277C, CX-2278C, CX-2279C and CX-2280C. In 2018, 475 Allergan R&D employees expended [ ] hours conducting R&D on all BOTOX®-related matters in the United States. CX-0018C at Q/A 73, 88; CX-2276C, CX-2277C, CX-2278C, CX-2279C, and CX-2280C; CX-2350C.

In addition, Allergan budgeted [ ] for its active research and development projects related to BOTOX® for 2019 and [ ] for these projects over the next ten years, the vast majority of which will be spent in the United States. CX-0008C at Q/A 61-64; CX-2350C (tab [ ]); CX-0016C at Q/A 34, 38.

In light of the foregoing evidence, Mr. Malackowski opined that Allergan's investments in R&D are significant and substantial, which demonstrate that Allergan has a domestic industry in BOTOX®. CX-0018C at Q/A 25, 26, 44, 106. *See also Rubber Resins ID* at 623–24 (crediting

> investments "in domestic research and development" in a trade secret case to find that a domestic industry exists); *Hand Dryers ID* at 38–42 (same); *Certain Strontium-Rubidium Radioisotope Infusion Sys.*, Inv. No. 337-TA-1110, Initial Determination at 143 (Aug. 1, 2019) ("*Radioisotope Infusion Sys. ID*") (holding that investments in R&D to obtain FDA approval constitute "a significant employment of labor and capital in the United States.

Compls. Br. at 222–25 (footnotes omitted).

Respondents argue, in part:

> Here, too, Complainants' calculations are once again beset with double-counting, date back more than 30 years, and fail to distinguish between domestic and foreign investments. The [
>
>], which alone cannot form the basis of a domestic industry. *See Certain Strontium-Rubidium Radioisotope Infusion Systems, and Components Thereof Including Generators*, Inv. No. 337-TA-1110, Comm'n Op. at 42, n.27 (Dec. 11, 2019),

Resps. Br. at 243–44.

The Staff argues, in part:

> Allergan alleges that since the launch of BOTOX in 1989, it has invested close to [ ] in research and development in the United States relating to BOTOX to improve its manufacturing process, to expand the number of cosmetic and therapeutic indications approved by the FDA, and to comply with FDA regulatory requirements, including clinical testing required by the FDA. CX-0008C (Marzouk WS) at ¶ 48; CX-0016C (Neervanan WS) at ¶¶ 10, 18–19, 32–33, 35; CX-0018C (Malackowski WS) at ¶¶ 82–83; CX-2327C (BOTOX R&D Data, tab "US&Int Botox"); CX-2350C (BOTOX R&D Data, tab "US&Int Botox"); CX-1042 (process of FDA approval process). In the Staff's view, the evidence shows that these research and development activities can be attributed to the existence of a domestic industry, even though they may not directly relate to the alleged misappropriated trade secrets. *See Rubber Resins*, ID at 621 (crediting investments "in domestic research and development" in a trade secret case); *Railway*

> *Wheels*, ID at 80–81 (crediting investments in R&D towards a domestic industry in articles that were the target of the accused railway wheels although the R&D was unrelated to the asserted trade secrets).

Staff Br. at 131.

The evidence shows that, from 1992 through Q1 2019, Allergan invested [ ] in research and development related to BOTOX®, of which [ ] was invested domestically. CX-0008C at Q/A 48-54; CX-0018C at Q/A 83; CX-2327C (BOTOX® R&D Data, tab "US&Int Botox"); CX-2350C (BOTOX® R&D Data, tab "US&Int Botox").[25] This includes R&D related to improving Allergan's manufacturing process, expanding the number of cosmetic and therapeutic indications approved by the FDA, and complying with FDA regulatory requirements, including clinical testing required by the FDA. CX-0016C at Q/A 10, 18-19, 32, 33, 35; CX-2350C, CX-2327C, CX-2385C; CX-1042 (process of FDA approval process).

More recently, from 2014 to 2018, Allergan has invested [ ] in R&D related to BOTOX, of which [ ] was invested domestically. CX-0008C at Q/A 55; CX-0018C at Q/A 83; CX-2350C (BOTOX R&D Data, tab "US&Int Botox"). *See Hyosung TNS Inc. v. Int'l Trade Comm'n*, 926 F.3d 1353, 1362 (Fed. Cir. 2019) (holding that "a past investment may, by virtue of its connection to ongoing . . . expenses, support a finding that the economic prong of the domestic industry requirement is met").

[25] The testimony and spreadsheet Allergan provided to demonstrate its investments in R&D (CX-2350C) includes a tab ("US&Int Botox") which sets forth Allergan's investments in "US" and "International" spending by year in different columns, the sums of which are identified in the spreadsheet along with the formulas used to "calculate," *i.e.*, sum, those investments. Complainants do not "double-count" any of Allergan's investments, because they do not purport to aggregate the investments across different categories to present a single "domestic industry" number.

From 2014 through 2018, the evidence demonstrates that Allergan has invested [ ] in R&D related to BOTOX®, of which [ ] was invested domestically. CX-0008C (Marzouk WS) at Q/A 55; CX-0018C (Malackowski WS) at Q/A 83; CX-2350C (BOTOX R&D Data, tab "US&Int Botox"). For the three approved BOTOX® Cosmetic indications alone, Allergan has invested [ ] in domestic R&D. CX-0018C (Malackowski WS) at Q/A 84; CX-0008C (Marzouk WS) at Q/A 58.

In view of the foregoing facts, the evidence demonstrates that Allergan has made significant domestic investments in research and development related to BOTOX (constituting BOTOX® Cosmetic and BOTOX® therapeutic collectively) and in BOTOX® Cosmetic individually.

d) Allergan's Activities in Westport, Ireland Relating to BOTOX®

Complainants argue, in part:

> Given the significant and substantial domestic investments highlighted above, Respondents argue that the Administrative Law Judge should disregard or discount those investments given that Allergan also maintains activities outside of the U.S. But there is no "Commission precedent supporting Respondents' position or the proposition that a comparison of domestic and foreign producers' assets must be performed," particularly in a non-statutory IP case such as this. *Male Prophylactics Comm'n Op* at 43, n.15 (reversing the Judge's holding that complainant failed to establish domestic industry because it failed to provide sufficient evidence comparing domestic and foreign expenditures). Even the case Respondents cite proves them wrong. Resps. Prehr'g Br. at 168 (citing *Carburetors Comm'n Op.* at 8–9, 17–18).
>
> In *Carburetors*, a statutory IP case, the Commission reiterated its position that "comparing complainants' domestic expenditures to its foreign expenditures is *one of the possible factors* that the Commission could *but, contrary to Respondents' argument, is not required to consider*."

> *Carburetors Comm'n Op.* at 8–9 (emphasis added) (citing *Certain Optoelectronic Devices for Fiber Optic Communications*, Inv. No. 337-TA-860, Comm'n Op. at 18–19 (May 9, 2014)). In fact, the Commission concluded that in order to "place the value of domestic investments in the context of the relevant marketplace," rather than comparing a complainants' domestic expenditures to its foreign expenditures or sales, one may "consider[] the value added to the product from a complainant's activities in the United States" instead. *Id*. at 18. As discussed above and herein, Allergan's domestic activities indisputably provide significant value add to the BOTOX product.
>
> . . .
>
> In their pre-hearing brief, Respondents assert that Allergan's foreign investments "outweigh" the "relevant" domestic investments, but there are at least two problems with that argument. Resps. Prehr'g Br. at 169. First, Respondents do not grapple with all of the undisputed evidence cited above. Instead, Respondents cherry pick Allergan's domestic investments at [ ] to use in their comparison to the Westport investments, which ignores all the other domestic investments that Allergan has made that are essential for the commercialization of BOTOX® and results in a skewed analysis. Second, Respondents cite no legal support for their suggestion that the domestic investments must "outweigh" the foreign investments—and Complainants are aware of none. To the contrary, in *Certain LED Lighting Devices*, Inv. No. 337-TA-1081, Initial Determination at 148, 2018 WL 7350925, at *84 (Dec. 19, 2018), the Judge determined that even if a complainants' investments are "comparatively low in absolute numbers"—which is *not* the case here—that "does not diminish the significance of the investment to the DI products in context" if the DI activities are "critical[] . . . to [complainant's] ability to commercialize the DI products." Because of the importance of Allergan's United States operations and because its aggregate domestic spending far exceeds the foreign expenditures, a domestic industry exists notwithstanding Allergan's activities in Westport.

Compls. Br. at 228–31.

Respondents argue, in part:

In *Carburetors*, the Commission recognized that there is no threshold monetary amount that dictates whether a complainant has met its obligation to prove a domestic industry. Rather, a complainant seeking to prove a relevant domestic industry must perform an analysis of the *relative* importance of the domestic activities in context. *Carburetors*, Comm'n. Op. at 8; *Lelo*, 786 F.3d at 883-84. Based upon this framework, the Commission in *Carburetors* agreed with the ALJ that the complainants' claimed U.S. investments were not substantial when considered in the context of the company's worldwide sales of the product at issue. *See, e.g.*, *id*. at 17.

Here, Complainants admit that Allergan's [ ] campus in Ireland is "[ ]." CX-2571C.8 (Allergan's Third Responses to Staff Interrogatories) at No. 1. Every BOTOX® product must be finished and filled in Ireland before being imported and sold in the U.S. RX-3158C.22 (Mulhern WS) at Q/A 114; *See also* JX-0037.27 (Allergan, Form 10-K, 2018) ("manufacturing of BOTOX® . . .is exclusively performed in Ireland.")

Given this evidence, it is Complainants' burden to perform a detailed comparison of investments in BOTOX® undertaken in the U.S. versus abroad. They have not done so. During discovery, Allergan produced limited information about investments Allergan has made at its Ireland facility; in fact, much of what Respondents know about investments in Ireland comes from public sources. For example, Allergan provided no information about the newest expansion to the Ireland plant and related equipment, *see* https://www.idaireland.com/newsroom/allergan-63-new-jobs-westport; CX-008C.18 (Marzouk WS) at Q/A 73-77. Indeed, Mr. Marzouk's entire testimony about Ireland consists of less than a page of highly general information. *Id*. It is thus unsurprising that Mr. Malackowski has not provided the necessary apples-to-apples analysis of investments in the U.S. versus abroad. *See, e.g.*, CPB at 164-66; CX-0018C.39-40 (Malackowski WS) at Q/A 108 (summarizing Mr. Malackowski's opinion that the "fill and finish" process at Ireland is "largely automated," but offering no detailed financial information on costs to undertake those activities). On this basis alone, Complainants have failed to meet their burden to show a domestic industry that is substantial in context.

Moreover, the minimal analysis Mr. Malackowski has performed is misleading or lacking in any evidentiary basis. For example, Mr. Malackowski has improperly inflated U.S. investments by including alleged BOTOX® R&D starting ***27 years ago***, which (even if it is a cognizable activity under subsection (a)(1)(A)(i)) is [ ]— of the total claimed U.S. investments. CX-0018C.13 Malackowski WS) at Q/A 44; CPB at 166. In addition, Allergan's plant and equipment in Ireland far outweigh the U.S. investments in manufacturing [ ], even crediting Complainants' flawed and inflated estimates. RX-3158.23, 25 (Mulhern WS) at Q/A 120, 130; CX-0018C.22-23 (Malackowski WS) at Q/A 67; CX-2345C (Fixed Asset Register June 2019). Thus, the foreign investments relating to BOTOX® manufacturing significantly outweigh any domestic investments. Yet Mr. Malackowski does not take this fact into account.

Mr. Malackowski also fails to properly examine the *value* added to BOTOX® in the United States versus abroad. S*ee, e.g.*, *Schaper*, 717 F.2d at 1373 (rejecting domestic industry allegations where "not enough significant value [was] added domestically to the [domestic industry products]" by complainant's domestic activities). As an initial matter, Complainants cannot show that the alleged costs and investments relating to U.S. BOTOX® API activity adds meaningful, let alone sufficient, value to the final imported BOTOX® product to support a finding of domestic industry, as Complainants refused to produce any discovery relating to its API. Order No. 24 at 2-3. The *only* "evidence" Complainants have presented of value contribution to BOTOX® in the U.S. versus abroad comes in the form of unsupported testimony of Allergan executive Dr. Sesha Neervannan. After the close of fact discovery, Dr. Neervannan stated that in his view the API for BOTOX® [ ]. CX-0016C.7 Neervannan WS) at Q/A 22. Allergan and Dr. Neervannan provided no analysis, data, or documentation to support this arbitrary calculation. Worse, this estimate is contradicted by Allergan documents that show the API contributes [ ]. *See, e.g.*, RX-2442C.39 [ ].

Resps. Br. at 237–40.

Mr. Malackowski testified that the contribution of the BOTOX®-related activities that occur at Westport to the BOTOX® product is substantially less than the contribution of Allergan's U.S.-based activities, because the "finish and fill" processes at Westport, Ireland are [

]. CX-0018C at Q/A 108; CX-0016C at Q/A 20. Dr. Neervannan testified that the domestically-manufactured API accounts for [

]. CX-0016C at Q/A 22. Thus, Allergan's domestic operations are qualitatively significant in comparison to its foreign operations.

Moreover, the labor expenses for BOTOX® incurred at Westport are [ ] than those incurred domestically. Allergan's direct labor expenses for BOTOX® at Westport were [ ] in 2017 and [ ] in 2016. CX-0008C at Q/A 77; CX-0018C at Q/A 108; CX-2315C (Westport BOTOX® Spend). By contrast, Allergan's annual domestic labor expenses for just its full-time employees who work on BOTOX® (excluding the vast majority of its R&D personnel) is more than [ ].

Although the overhead expenses at the Westport facility [

]. CX-0008C at Q/A 74; CX-0018C at Q/A 108.

The acquisition value of the BOTOX®-related assets at Westport was approximately [ ], capitalized from 2001 to 2019, with a current book value of approximately [ ] as of June 30, 2019. CX-0008C at Q/A 75-76; CX-

2345C and CX-2347C (Fixed Asset Register for BOTOX®). This is only a fraction of the amount Allergan has invested in BOTOX® domestically. Allergan's investments in domestic research and development from 1992 to Q1 2019, domestic plant and equipment, and just one years' worth of domestic employee salaries exceed [ ]. Viewed in context, the administrative law judge finds that Allergan's operations in Ireland do not negate Allergan's significant and substantial investments in the domestic industry. *Cf. Certain Carburetors and Prods. Containing Such Carburetors*, Inv. No. 337-TA-1123, Comm'n Op. at 18–20 (Oct. 28, 2019).

2. Allergan's Investments Relating to MT10109L

Complainants argue, in part:

> Allergan has already invested significant resources related to MT10109L, expressed in terms of costs, employees, and hours. CX-0008C at Q/A 81-88; CX-0018C at Q/A 99-104; CX-2350C (tab "Annual Medytox"); CX-2327C (tab "Annual Medytox"); *see also Radioisotope Infusion Sys. ID* at 143 (holding that investments in R&D to obtain FDA approval constitute "a significant employment of labor and capital in the United States").
>
> From 2013 through Q1 2019, Allergan invested [ ] in MT10109L-related R&D, of which [ ] was spent domestically. CX-0008C at Q/A 83; CX-2350C (tab "Annual Medytox"); CX-0018C at Q/A 100. Allergan's R&D work for MT10109L includes the [ ], virtually all of which occurs at Allergan's facilities in [ ]. CX-0016C at Q/A 51-56; *see also* CX-0018C at Q/A 101. And Allergan employs numerous R&D personnel who allocate their time between MT10109L and non-MT1019L projects—[ ] employees in 2014, [ ] in 2015, [ ] in 2016, [ ] in 2017, and [ ] in 2018. *Id*. at Q/A 102; CX-0008C at Q/A 79-82; CX-2276C, CX-2277C, CX-2278C, CX-2279C, and CX-2280C.

> Mr. Malackowski presented unrebutted testimony and his analysis that between 2014 and 2018, these research and development employees spent over [ ] aggregated hours on R&D relating to MT10109L in the United States. CX-0018C at Q/A 103.
>
> . . .
>
> Allergan budgeted [ ] for its R&D projects related to MT10109L for 2019, of which [ ] is budgeted for [ ]. CX-0008C at Q/A 86; CX-2350C (tabs "Annual Medytox" and "Internal External (Medytox)"); CX-0018C at Q/A 100; CX-0016C at Q/A 56. [ ] of this money was spent domestically. *See* CX-0016C at Q/A 56.
>
> Mr. Malackowski opined that based on the foregoing investments, Allergan has established a domestic industry in MT10109L, irrespective of whether MT10109L is presently available for commercial sale. CX-0018C at Q/A 99, 105-06. Commission precedent confirms that "commercial availability . . . is not necessary to show . . . that a domestic industry exists," nor is FDA approval. *Radioisotope Infusion Sys. ID* at 132–35; *id.* at 149 ("Even without FDA approval, however, Bracco's industry presently exists."); *see also Certain Road Constr. Machs.*, Inv. No. 337-TA-1088, Initial Determination at 74-76 (Feb. 14, 2019) (domestic industry exists even without commercial sales of the machines incorporating the patented technology); *cf. Certain Non-Volatile Memory Devices*, Inv. No. 337-TA-1046, Comm'n Op. at 39-44, 2018 WL 6012622, at **25-27 (Oct. 26, 2018) (finding a domestic industry "in the process of being established" based on the complainant's "substantial investments in research, development, and engineering," even though it "has not yet arrived at the final stages of commercializing" the product).

Compls. Br. at 231–34.

Respondents argue, in part:

> MT10109L is manufactured exclusively in Korea and imported into the United States by Allergan. RX-2967C.6 (Medytox's Responses to Daewoong's Third RFAs). Complainants have claimed two categories of Allergan "investments" in MT10109L: first, the payments Allergan has made or will make to Medytox under the 2013

Agreement, in exchange for the right to commercialize MT10109L for sale; and second, costs associated with FDA R&D and regulatory approval. Neither category is cognizable.

With respect to the upfront and milestone payments Allergan has pledged under the 2013 Agreement, these represent investments by a mere importer (Allergan) in order to sell and market an imported product made by Medytox. RX-3158C.18 (Mulhern WS) at Q/A 102. The Commission has never before considered in-licensing payments, particularly payments to a foreign entity, to be a valid basis for a domestic industry, and it should not start now.

Complainants' claimed FDA R&D and regulatory activities, are likewise performed by a mere importer and cannot constitute a domestic industry on their own. Because a domestic industry under subsection (a)(1)(A)(i) must relate to domestic manufacturing, Allergan's alleged R&D/regulatory investments in MT10109L fail as a matter of law.

. . .

Even if Allergan's investments in MT10109L FDA R&D are considered relevant, which they are not, they are not qualitatively or quantitatively significant, and thus cannot support a domestic industry. For example, there is [ ] (CPB at 167), and Complainants' expert Mr. Malackowski has not provided any credible allocation of the extent to which the Allergan employees who work on MT10109L as well as other products spend their time on the former as opposed to the latter. RX-3158C.19 (Mulhern WS) at Q/A97. Moreover, Mr. Malackowski opted not to compare Allergan's U.S. investments in MT10109L to worldwide development spending for the product. *Id*. at Q/A 99. Medytox's interrogatory responses suggest that it has spent at least [ ] in Korea in support of its development and manufacturing of MT10109L — a fact that Mr. Malackowski failed to consider entirely. *See, e.g.*, CX-2575C.16-19 (Medytox's R&O's to Staff's First Set of Interrogatories) at No. 6 (claiming [ ] of investments by Medytox in R&D and manufacturing of MT10109L in Korea); RX-3158C.20 (Mulhern WS) at Q/A 100. Allergan is a mere importer of MT10109L, and its meager domestic activities cannot

> support a domestic industry in this context. *See Corning Glass Works* v. *Int'l Trade Comm'n*, 799 F.2d 1559, 1569-70 (Fed. Cir. 1986) ("*Corning Glass*") (refusing to allow an intellectual property owner to "merely license the importation of products from abroad and claim injury within the meaning of section 337 to exclude unlicensed imports, despite having contributed little or nothing in the way of opportunities for employment of our industrial workers, one of the stated objectives of the Tariff Act of 1930"); *Certain Carburetors & Prods. Containing Such Carburetors*, Inv. No. 337-TA-1123, Comm'n Op. at 18 (Oct. 28, 2019) ("*Carburetors*") (discussing the importance of performing a contextual analysis of domestic industry).
>
> Finally, none of the R&D investments Mr. Malackowski claims in MT10109L [
>
>] relate to the asserted trade secrets or have any documentary support, rendering them non-cognizable. RX-3158C.19 (Mulhern WS) at Q/A 98. *See also Certain Strontium-Rubidium Radioisotope Infusion Systems, and Components Thereof Including Generators*, Inv. No. 337-TA-1110, Comm'n Op. at 42, n.27 (Dec. 11, 2019) ("…efforts to obtain regulatory approval may not on their own distinguish a complainant's activities from those of an importer.") For these reasons, even if Allergan's R&D-related investments in MT10109L can be considered, they do not amount to a domestic industry.

Resps. Br. at 233–35.

The Staff argues, in part:

> Allergan partnered with Medytox in 2013 to develop and introduce MT10109L to the U.S. market. CX-0016C (Neervanan WS) at ¶ 39; *see also* JX-0050C (Allergan-Medytox License Agreement). Since 2013, Allergan has paid Medytox [
>] and has agreed to pay Medytox [
>]. CX-0018C (Malackowski WS) at ¶ 104; CX-2237C (Burke email (Mar 6, 2018)).

. . .

> The evidence demonstrates that Allergan has made significant domestic investments in research and development related to MT10109L.

Staff Br. at 133–35.

The evidence shows that Allergan has invested significant resources related to MT10109L, expressed in terms of costs, employees, and hours. CX-0008C at Q/A 81-88; CX-0018C at Q/A 99-104; CX-2350C (tab "Annual Medytox"); CX-2327C (tab "Annual Medytox").

From 2013 through Q1 2019, Allergan invested [ ] in MT10109L-related R&D, of which [ ] was spent domestically. CX-0008C at Q/A 83; CX-2350C (tab "Annual Medytox"); CX-0018C at Q/A 100. Allergan's R&D work for MT10109L includes [ ] of which occurs at Allergan's facilities in [ ]. *See* CX-0016C at Q/A 51-56; CX-0018C at Q/A 101. Allergan employs numerous R&D personnel who allocate their time between MT10109L and non-MT1019L projects—[ ] employees in 2014, [ ] in 2015, [ ] in 2016, [ ] in 2017, and [ ] in 2018. *Id*. at Q/A 102; CX-0008C at Q/A 79-82; CX-2276C, CX-2277C, CX-2278C, CX-2279C, and CX-2280C.

Allergan also employs numerous R&D personnel who allocate their time between MT10109L and non-MT1019L projects—[ ] employees in 2014, [ ] in 2015, [ ] in 2016, [ ] in 2017, and [ ] in 2018. CX-0008C at Q/A 79–82; CX-0018C at Q/A 102; CX-2276C – CX-2280C (BOTOX® Actual Hours for 2014 to 2018, respectively). Between 2014 and 2018, these R&D employees spent over [ ] aggregated hours on R&D relating to MT10109L in the United States.

R&D for MT10109L	**2014**	**2015**	**2016**	**2017**	**2018**	**Total**
Total R&D Employees	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Total R&D Hours	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
U.S. % of Total R&D Spend	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Total U.S. R&D Hours	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

CX-0018C (Malackowski WS) at Q/A 102–03; CX-2276C – CX-2280C; CX-2350C.

Allergan budgeted [ ] for its R&D projects related to MT10109L for 2019. CX-0008C (Marzouk WS) at Q/A 86; CX-2350C. "[ ] of this money will be spent domestically." CX-0016C (Neervanan WS) at Q/A 56.

C. Whether Complainants' Domestic Industry Is Being Substantially Injured

Section 337(a)(1)(A) requires a complainant to show that the "threat or effect" of the alleged unfair acts is "to destroy or substantially injure an industry in the United States." 19 U.S.C. § 1337(a)(1)(A). To determine whether unfair acts have the effect of substantially injuring the domestic industry, the Commission has considered a "broad range of indicia." *Certain Electric Power Tools, Battery Cartridges and Battery Chargers* ("*Electric Power Tools*"), Inv. No. 337-TA-284, Unreviewed Initial Determination at 246, USITC Pub. No. 2389 (1991)), *see* Notice of Commission Determination Not to Review a Final Initial Determination Finding a Violation of Section 337; Request for Written Submissions Regarding Remedy, Bonding, and the Public Interest (EDIS Doc. ID No. 416143) (Dec. 17, 2009). These factors include, but are not limited to: (1) the respondent's volume of imports and penetration into the market; (2) the complainant's lost sales; (3) underselling by the respondent; (4) the complainant's declining production, profitability and sales; and (5) the harm to complainant's goodwill and reputation. *See Railway Wheels*, Unreviewed ID at 81–82.

In addition, the Commission must also consider the competitive environment, such as whether the accused products are sold in the same channels of commerce, target the same market segment, and/or are positioned as the same or similar products as the domestic industry products. *Rubber Resins*, Comm'n Op. at 64. Based on an assessment of these factors, and "[w]here unfair methods and acts have resulted in conceivable loss of sales, a tendency to substantially injure such industry has been established." *Railway Wheels*, Unreviewed ID at 82 (quoting *Electric Power Tools ID* at 248–49).

1. Lost sales of and profits from BOTOX®

Complainants argue, in part:

> The evidence proffered with respect to each of the relevant factors demonstrates that there has already been a significant injury to Complainants' domestic industry for BOTOX® and that there will continue to be further injury if Respondents are not enjoined from further importation and sale of the Accused Products in the United States. The fact that Respondents chose not to cross-examine any of the Allergan fact witnesses, nor Complainants' economic expert, on Complainants' claims of injury highlights how clear and pervasive the injury is in this case.
>
> . . .
>
> Jeuveau was launched in the United States in May 2019 with the specific intent of competing with and taking market share from BOTOX® Cosmetic. Evolus has already imported a significant volume of Jeuveau [ ] into the United States. CX-1704C (Sabad Dep.) at 78:7-15, 94:17-25, 97:7-98:16, 144:6-13; CX-2440C (Evolus Forecast); CX-2535C (YC Kim Dep.) at 119:8-122:5, 122:14-124:25, 126:15-128:9. These vials directly compete with BOTOX® and are sold or distributed using the same marketing channels that Allergan uses to sell BOTOX®. CX-0009C (McKenna WS) at Q/A 35-39, 50; *see Railway Wheels ID* at 84 (finding substantial injury to a domestic industry where "[t]he evidence demonstrates that respondents are using the same marketing channels that Amsted uses to sell railway wheels").

According to Evolus, Jeuveau "was designed from the outset to compete with the market leader"—*i.e.*, BOTOX®. CX-2381C.8 (Evolus Analyst/Investor Day Transcript); CX-1705C (Moatazedi Dep.) at 178:20-179:7; CX-1247.2 (Mad Money Transcript). In that regard, Evolus has formulated and executed a marketing strategy "to capture market share against [A]llergan." CX-2428.2 (Evolus Commercial Strategy). Evolus [

]. CX-2419C.2 (Evolus Board Slides); Hr'g Tr. (Moatazedi) at 907:10-908:10; *see also* CX-2535C (YC Kim Dep.) at 145:15-25 (reading an email (CX-0909C) from Daewoong's CEO referencing [

]; CX-0909C.1 (S.H. Jeon Email, 9/27/18) (stating that Daewoong was [

]). Evolus's CEO, David Moatazedi, agreed at the Hearing that "because Allergan is the market leader, it makes sense for [Evolus] to focus one of your marketing efforts against Allergan." Hr'g Tr. (Moatazedi) at 908:2-10 ("And naturally, you're going to focus on the gold standard [*i.e.*, Allergan] rather than the second or third player in the market."); *see also Certain Light-Emitting Diode Prods.*, Inv. No. 337-TA-947, Initial Determination at 482-83 (July 29, 2016) ("*Light-Emitting Diode Prods. ID*") (finding substantial injury to a domestic industry where "Respondent and Complainant are rivals for consumer dollars" and the "[e]vidence also suggests that Feit Respondents do consider themselves to be in competition with Complainant because they 'benchmark' their LED products against Complainant's [and] . . . . appeal to customers by comparing their products to Complainant's").

Evolus promotes Jeuveau as "the first real competitor to BOTOX®." Hr'g Tr. (Moatazedi) at 913:7-12; CX-2377C.2 (Evolus Leadership Summit). Principally, as explained above, Jeuveau is the first and only 900 kDa alternative to BOTOX® in the United States. CX-0009C (McKenna WS) at Q/A 26; Hr'g Tr. (Moatazedi) at 911:7-12. Mr. Moatazedi (who until May 2018 served as Allergan's Vice President of Sales and Marketing for Facial Aesthetics) refers to the 900 kDa molecule as the "scientific gold standard" among botulinum toxins. CX-1705C (Moatazedi Dep.) at 45:24-46:10; Hr'g Tr. (Moatazedi) at 911:13-912:9. Evolus views the 900 kDa molecule of Jeuveau as a key factor in competing with BOTOX®

Cosmetic. CX-0018C (Malackowski WS) at Q/A 147-48; CX-2604C.6 (Errata); CX-1241.4 (Evolus Q2 2019 Earnings Call) (describing the 900 kDa molecule as a key factor in converting customers from BOTOX® Cosmetic to Jeuveau); Hr'g Tr. (Moatazedi) at 911:13-17 ("Q. And as part of your marketing to physicians, Evolus points this out because you believe that the 900 kilodalton products, BOTOX® and Jeuveau, are the gold standard for this type of product? A. That's correct.").

The BTX products competing with BOTOX® Cosmetic prior to Jeuveau—Dysport® and Xeomin®—have struggled because they behave differently as a result of not being 900 kDa products. *See* CX-0009C (McKenna WS) at Q/A 20, 23; Hr'g Tr. (Moatazedi) at 911:13-24. Dysport® is diluted and dosed differently than BOTOX® Cosmetic, and thus has different diffusion characteristics, and Xeomin® is known not to last as long as BOTOX® Cosmetic. CX-0009C (McKenna WS) at Q/A 17, 19–21, 23; CX-2218C (Competitive Analysis of Dysport®); CX-2219C (Competitive Analysis of Xeomin®); CX-0018C (Malackowski WS) at Q/A 147-48; CX-2604C.6 (Errata). Neither product is viewed as a true alternative to BOTOX® Cosmetic. CX-0018C (Malackowski WS) at Q/A 148; CX-2604C.6 (Errata).

Jeuveau, by contrast, is promoted by Evolus as a "frictionless alternative" to BOTOX® Cosmetic. *See* CX-2256.14 (Evolus Analyst Day Presentation). The similarities between the Jeuveau and BOTOX® Cosmetic 900 kDa toxin complexes enable Jeuveau to be similar, if not identical, to BOTOX® Cosmetic in terms of preparation and dosing, allowing physician customers of BOTOX® Cosmetic to easily transition to Jeuveau. CX-0018C (Malackowski WS) at Q/A 152; CX-2604C.6-7 (Errata); CX-2299C (Goldman Sachs Report); Hr'g Tr. (Moatazedi) at 910:19-911:6. Evolus further promotes the similarities between Jeuveau and BOTOX® through a "head-to-head" study that Evolus designed showing "non-inferiority" of Jeuveau to BOTOX® Cosmetic. CX-2256.37 (Evolus Analyst Day Presentation); Hr'g Tr. (Moatazedi) at 908:12-909:23. According to Evolus, this study has been "critical to the success Jeuveau has achieved so far," "giv[ing] confidence to the market and the performance of the product, relative to [BOTOX®]." CX-1705C (Moatazedi Dep.) at 115:22-116:8; Hr'g Tr. (Moatazedi) at 909:2-23. Notably, Evolus has not performed

> comparative studies between Jeuveau and any other BTX products on the market, [ ]. Hr'g Tr. (Moatazedi) at 909:24-910:1; CX-1705C (Moatazedi Dep.) at 50:19-51:7, 116:9-11.
>
> Furthering Jeuveau's ability to compete with the Domestic Industry Products is the fact that many key members of Evolus's management team (including Mr. Moatazedi himself) are former high-level Allegan employees with significant BOTOX® experience. *See* CX-0018C (Malackowski WS) at Q/A 149-50; CX-2604C.6 (Errata); Hr'g Tr. (Moatazedi) at 897:6-17. In fact, six of the nine members of Evolus's management team are former Allergan employees, including Evolus's President and CEO (David Moatazedi), the Vice President of Corporate Communications & PR (Crystal Muilenburg), Vice President of Sales (Kurt Knab), CFO and VP of Business Development (Lauren Silvernail), Chief Medical Officer and Head of R&D (Rui Avelar), and Chief Marketing Officer (Michael Jafar). CX-0018C (Malackowski WS) at Q/A 149-50; CX-2604C.6 (Errata). All of these individuals – and especially those with senior executive-level knowledge of and experience with BOTOX® – give Evolus valuable insight that allows Evolus to compete more effectively with Allergan. For example, as recently as early 2018, Mr. Moatazedi was "the most senior person in the company [Allergan] with direct responsibility for BOTOX® Cosmetic" and was thus "privy to all strategic thinking and planning . . . with regard to the commercial side of BOTOX® Cosmetic[.]" Hr'g Tr. (Moatazedi) at 897:9-17. Significantly, one of the last things Mr. Moatazedi did before leaving Allergan was to assess the competitive threat to BOTOX® posed by Evolus. *Id.* at 897:18-898:5. Third party analysts have recognized the competitive advantage Evolus gains from the former Allergan employees. For example, Goldman Sachs reported that, "Evolus' management team consists almost exclusively of former Allergan employees, suggesting expertise in the field and a track record of success." CX-2299C.7 (Goldman Sachs Report); CX-0018C (Malackowski WS) at Q/A 149-50; CX-2604C.6 (Errata).

Compls. Br. at 237–41 (footnote omitted).

Respondents argue, in part:

As discussed above, BOTOX® is not an appropriate domestic industry product, since it bears no connection whatsoever to the trade secrets or the conduct at issue in this case. But even if BOTOX® can be considered for domestic industry and injury purposes, Complainants have not shown that, in the few months since Jeuveau® has been on the market, it has substantially injured BOTOX®. To the contrary, as recently released Allergan financials for 2019 make clear, BOTOX® sales and revenues continue to rise, consistent with [ ]. RX-3564.3 (Allergan Q4 and YE 2019 Financial Results). An analysis of the various factors relevant to actual injury follows.

. . .

As of the close of fact discovery on July 17, 2019, Evolus had sold a total of only [ ] units of Jeuveau®. CX-0018C.42 (Malackowski WS) at Q/A 118; RX-3158C.33 (Mulhern WS) at Q/A 169; RDX-0001C.9 (Mulhern Demonstrative); RX-3055C (Mulhern Exhibit 30); CX-2451.709 (Email re Daily sales report), CX-2429C.479 (Slides re Evolus June Forecast); RX-0562 (Allergan 10-Q, June 30, 2019), RX-0561.54, 60 (Allergan 2018 10-K). These sales are just [ ] of worldwide BOTOX® revenue. *Id.* This small volume and low level of market penetration is not substantial. *See, e.g., Certain Combination Locks*, Inv. No. 337-TA-45, Comm'n Op. at 9-10 (Feb. 16, 1979) ("*Combination Locks*") (rejecting 2% of Complainant's production as non-substantial).

Now that both Evolus' and Allergan's FY 2019 financials are in, a comparison of actual 2019 revenues for Jeuveau® versus BOTOX® is possible. In 2019, Evolus made $33.3 to $34.3 million in revenue from Jeuveau® sales in the United States, and Allergan made in total $3.79 billion in revenue from BOTOX® sale — $991.3 million from domestic sales of BOTOX® Cosmetic, $671.7 million in international sales of BOTOX® Cosmetic, $1.74 billion from domestic sales of BOTOX® Therapeutic, and $389.1 million in international sales of BOTOX® Therapeutic. *Compare* CX-2617.1-5 (Evolus Q4 2019 Revenue Announcement) *with* RX-3564.10 (Allergan Q4 2019 Results). Conservatively, Evolus' 2019 domestic revenues from Jeuveau® are approximately 0.9% of Allergan's worldwide 2019 BOTOX® revenue, less than

1.3% of Allergan's U.S. BOTOX® revenue, and less than 2% of Allergan's U.S. BOTOX® Cosmetic revenue. *Id*. In other words, even with several more months of sales data, the penetration rate is still minimal.

Moreover, Allergan's sales have continued to grow, significantly, since Jeuveau® entered the market. RX-3158C.33-34 (Mulhern WS) at Q/A 173; RDX-0001C.9 (Mulhern Demonstrative); *See supra* at Section VII.E.4.a. Allergan's 2019 data shows that its domestic BOTOX® Cosmetic sales grew by 9.3% in 2019, [ ]. RX-3564.3 (Allergan Q4 and YE 2019 Financial Results); RX-3158.34, 48 (Mulhern WS) at Q/A 176, 270-271; RX-3400.1 (Allergan's 3rd Quarter Financial Results); RX-0097C.79 [ ].

. . .

Jeuveau® is only FDA-approved for cosmetic indications, not for therapeutic. There is no evidence of off-label usage of Jeuveau® for therapeutic applications, and testimony by Allergan executive Colleen McKenna suggests that [ ]. RX-3004C.6-7, 9 (McKenna Dep. Desg. at 24:21-25:16, 33:19-25). Sales of Jeuveau® therefore cannot displace any BOTOX® Therapeutic and there is no evidence that it has. RX-3158.31 (Mulhern WS) at Q/A 166.

As for BOTOX® Cosmetic, Complainants' expert Mr. Malackowski suspects Jeuveau® may reach [ ] market share (based on internal Evolus projections from the time of the product's launch), and that a full [ ] of that market share would come at the expense of BOTOX®. CX-0018C.43-44, 48 (Malackowski WS) at Q/A 128-132, 139-140. These aggressive estimates are belied by the evidence of how Jeuveau® actually has fared and how it has generated its sales.

First, Evolus CEO Mr. Moatazedi testified at the evidentiary hearing that Jeuveau® has reached, at most, a *7.5%* market share in unit terms — [ ]. Hearing Tr. 902:23-903:1. Second, Mr. Malackowski's assumption that [ ] cannot be reconciled with the evidence that a substantial amount of

Jeuveau®'s sales come at the expense [

]. For example, internal Allergan documents [

]. RX-0552C.26 (Allergan Corporate Overview presentation). Even Allergan's CEO, Brent Saunders stated, at a public conference, "[H]onestly, how do you guys think that this competition [with Jeuveau®] is going to heat up. ***They're not going to go after us [BOTOX®]. They have to go after Dysport and Xeomin . . .*** " RX-2382.15 (Transcript of Citi Global Healthcare Conference) (emphasis added).

In January 2020, RBC Capital Markets released a survey of the facial toxin market, based on a series of questions to 50 physicians. Among the findings of the survey was that "Most of Jeuveau®'s overall market share gains have come largely from Dysport and XEOMIN, with BOTOX® relatively unaffected." RX-3561.3 (RBC Capital Markets - Deep dive into BOTOX®). Internal data from [ ]. RX-3158C.33-35 (Mulhern WS) at Q/A 184-95; Hearing Tr. 938:12-19.

In addition, it is undisputed that the market for botulinum toxin products is growing; that BOTOX®'s sales have increased every year for the last several years; and that Allergan expects continued growth of BOTOX® sales in the [ ]. RX-3158C.49 (Mulhern WS) at Q/A 282; RX-3400 (Allergan Q3 2019 Financial Results); RDX-0001C.16 (Mulhern Demonstrative); RX-3148C (Mulhern Exhibit 14); CX-2334C [

], at tab 'Botox Cx.'. Complainants have provided no evidence rebutting the plausible assumption that many of Jeuveau®'s sales are coming from completely new customers to the market (*i.e.*, the "toxin naïve") — an outcome very much in line with Evolus' marketing strategy. RX-3158.46 (Mulhern WS) at Q/A 257-260; RX-0540C.2 (Aesthetic Insights Article); RX-3162C.8-9, 13 (Moatazedi WS) at Q/A 46-47, 68.

Allergan also employs a variety of bundling and discounting tools to ensure that its providers and customers are [ ]. *See supra* at Section II.G.1.b. These Allergan strategies

> have contributed to the fact that to date, Jeuveau® sales [ ].
>
> Mr. Malackowski's counterfactual assumptions are no substitute for detailed evidence of what portion of Jeuveau® sales, if any, have displaced BOTOX® Cosmetic sales. Given Complainants' failure to provide a credible estimate of lost BOTOX® Cosmetic sales to Jeuveau®, the countervailing evidence suggesting limited displacement of BOTOX® Cosmetic, and no evidence of any lost BOTOX® Therapeutic sales, this factor weighs strongly against a finding of actual substantial injury to the alleged BOTOX® domestic industry.

Resps. Br. at 250–54 (footnotes omitted).

The Staff argues, in part:

> Complainants proffered evidence to demonstrate a nexus between the misappropriation of the asserted Medytox trade secrets by Daewoong in the importation of accused products into the United States, or in the sale of the imported accused products by Respondents, to the injury to the domestic industry suffered by Complainants. 19 U.S.C. § 1337(a)(1)(A)(i). Complainants presented evidence regarding injury, or a threat of injury, in the following categories: (1) lost sales or profits (CPB 174–79) and (2) price erosion (CPB at 179–84). The evidence satisfies Complainants' burden of showing actual and/or threat of substantial injury to the alleged domestic industry.

Staff Br. at 135.

The administrative law judge finds that complainants have suffered an actual injury to the BOTOX® domestic industry. The evidence demonstrates that Jeuveau®'s 2.61% market share came entirely at the expense of BOTOX® Cosmetic. CX-0018C at Q/A 112–17; CX-2433. Each percentage point of lost market share represents more than [ ] in lost profit per year for Allergan. CX-0018C at Q/A 112–17; CX-0009C (McKenna WS) at Q/A 82–85. Thus, a 2.61% loss in market share for BOTOX®

Cosmetic represents over [ ] in annualized lost profits for Allergan. CX-0018C at Q/A 112–17; CX-0009C at Q/A 82–86. As of July 17, 2019 (the last day for which Evolus produced sales information for Jeuveau®), Allergan lost approximately [ ] in gross profit due to the [ ] of Jeuveau® sold, with Evolus unfairly gaining between [ ] in gross profit. CX-0018C (Malackowski WS) at Q/A 118; CX-2429C (Evolus June Forecast); CX-2451C (Daily Sales Report from July 17, 2019); CX-2596C [ ]; CX-2433C (Guidepoint Tracker); CX-2338C (McKenna email (June 22, 2019)); CX-2175C (Nabota Business Plan); CX-2358C (Evolus Strategic Plan).

Jeuveau® has attained approximately 7.5% market share through the end of 2019. Moatazedi Tr. 904–905 [ ]. The GuidePoint data also showed Allergan's market share declining by 6.1 percentage points from 75% to 68.9% between the launch of Jeuveau® to the end of 2019. *Id*. at 905 [ ]. Mr. Moatazedi admitted that Evolus "[ ]." *Id*. at 903–04. "[N]othing in § 337 requires a showing that the domestic industry will be utterly deprived of profitability." *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1487 (Fed. Cir. 1986). "Where unfair methods and acts have resulted in conceivable losses of sales, a tendency to substantially injure such industry has been established." *Id*., citing House Comm. on Ways and Means, Trade Reform Act of 1973, H.R.Rep. No. 571, 93d Cong. 1st Sess. 78 (1973); *accord In re Von Clemm*, 229 F.2d 441, 445 (C.C.P.A. 1955).

Moreover, the decline in BOTOX® Cosmetic's market share at the expense of Jeuveau® is expected to continue. Evolus appears confident that Jeuveau® will achieve

the number two U.S. market position within 24 months of launch. *See* CX-1179.1 (Evolus Press Release) (Evolus announcing that Jeuveau® attained the number three market position in the U.S. BTX market within "90 days of launch . . . ahead of expectations," and Evolus "remain[s] highly confident in [its] ability to achieve the number two U.S. market position within 24 months of launch"); CX-2429C.16 (Evolus June Forecast); CX-1260.7–8 (Q2 Earnings Call); CX-2617.1-2 (Evolus Press Release).

Evolus projects a cumulative [ ] percent market share for Jeuveau® in 2019, even though Jeuveau® was not launched until about halfway into the year. CX-2429C.15 (Evolus June Forecast). Thus, Jeuveau® likely had over a [ ] percent monthly market share as of the end of 2019. CX-0018C (Malackowski WS) at Q/A 123. Evolus further projects that Jeuveau® will reach [ ] percent U.S. market share in its first year following launch (*i.e.*, by May 2020). *Id*. at Q/A 124; CX-2429C.16 (Evolus June Forecast). Similarly, according to an internal pricing sensitivity analysis performed by Evolus, at the current net average selling price for Jeuveau®, Evolus expects Jeuveau® [

]. CX-0018C at Q/A 127; CX-2385C (Pricing Analysis). Evolus projects its revenue and sales for Jeuveau® to increase rapidly from 2019 to 2022, with [

]. CX-1705C (Moatazedi Dep.) at 160–62 (confirming projections from a June 2019 internal investor relations update).

The evidence shows that at least [ ] percent of Jeuveau®'s future [ ] percent market share likely will come at the expense of BOTOX® Cosmetic, translating into a [ ] percentage point loss in market share for BOTOX® Cosmetic. CX-0018C (Malackowski WS) at Q/A 129–32. For example, a 2017 study regarding the U.S. BTX market

commissioned by Evolus determined that, depending on price point, [ ] percent of Jeuveau®'s market share will come from BOTOX® Cosmetic. CX-2384C (Neurotoxin Quantitative Research). Similarly, an internal pricing sensitivity analysis performed by Evolus showed that, at an effective price of [ ] per vial [ ], Evolus expected a market share of [ ] percent for Jeuveau® and [ ] percent for BOTOX® Cosmetic, down from BOTOX® Cosmetic's pre-Jeuveau® market share of around [ ] percent; the nearly [ ] percentage point drop in BOTOX® Cosmetic market share equates to approximately [ ] percent of Jeuveau®'s [ ] percent market share. CX-2385C (Pricing Analysis); CX-0018C at Q/A 132. [ ] third party estimates of BOTOX® Cosmetic's market share loss due to Jeuveau®, are consistent with Evolus' estimates. *See* CX-0018C at Q/A 133; CX-2333C [ ]; CX-2270 (Wall Street Journal article); CX-2298 (Cantor Fitzgerald Report); CX-2300 (RBC Capital Markets Report); CX-2301 (Piper Jaffray Report).

A [ ] percent market share for Jeuveau®, with [ ] percent of that market share coming at the expense of BOTOX® Cosmetic, would be a [ ]-percentage-point market share decrease for BOTOX® Cosmetic. CX-0018C (Malackowski WS) at Q/A 139–40. The evidence shows that a [ ]-percentage-point decrease represents an annual loss to Allergan of more than [ ] in profit. *Id*.

2. Price Erosion of BOTOX®

Complainants argue, in part:

> Jeuveau has [ ], taking profits from Complainants. Evolus openly admits that it prices Jeuveau to physicians [ ]. CX-

0018C (Malackowski WS) at Q/A 177; CX-2604C.9 (Errata); CX-1708C (Jafar Dep.) at 62:18-63:4; CX-0009C (McKenna WS) at Q/A 61; Hr'g Tr. (Moatazedi) at 913:13-914:11. This means that physicians can [

]. *Id.* at 913:13-914:11 (Jeuveau has "improved profitability" for doctors).

Evolus launched Jeuveau using what is called "[ ]," meaning that the price of Jeuveau was [ ]; that is, if the price of BOTOX® Cosmetic were reduced, Evolus would also reduce the price of Jeuveau to [

]. CX-2419C (Evolus Board Slides); CX-1705C (Moatazedi Dep.) at 193:18-194:3. [

]. Hr'g Tr. (Moatazedi) at 917:4-11; CX-0018C (Malackowski WS) at Q/A 117. In short, Evolus has already [ ].

Ms. Mulhern argued that comparisons of pricing on BOTOX® and Jeuveau are difficult because Allergan ["

]. RX-3158C (Mulhern WS) at Q/A 358. But Mr. Moatazedi undermined this argument, testifying at the Hearing that Evolus discounts Jeuveau "[ ]." Hr'g Tr. (Moatazedi) at 916:11-17. In other words, the discounts on Jeuveau are significant enough that physicians save money [

]. Indeed, Evolus has publicly stated that its pricing objective is to "break the bundle" – referring to Allergan's bundle discounts. CX-2256.15, 32 (Evolus Investor Day).

Exacerbating the harm to the domestic industry, Evolus has pricing flexibility that Allergan does not (beyond being able to price Jeuveau at such a large discount to BOTOX® Cosmetic). This is due in large part to the fact

that Jeuveau is approved for only a cosmetic indication. *See* CX-0018C (Malackowski WS) at Q/A 156-57; Hr'g Tr. (Moatazedi) at 917:12-919:11 (Mr. Moatazedi agreeing that Evolus's cosmetic-only approach "gives [Evolus] more flexibility in [its] pricing decisions"). By contrast, as Mr. Moatazedi is personally aware, the fact that Allergan and other providers of BTX products in the United States sell their BTX products for both cosmetic and therapeutic indications constrains their ability to discount their products due to Centers for Medicare & Medicaid Services ("CMS") regulations. CX-0018C (Malackowski WS) at Q/A 156-57; CX-0009C (McKenna WS) at Q/A 62. Specifically, regulations limit the amount reimbursed by CMS based on a weighted ASP that considers all ASPs for a product, including prices for different indications and vial sizes. Thus, while the regulations do not require Allergan to set the prices of BOTOX® Cosmetic at a particular level, they impact pricing in the sense that a price reduction for BOTOX® Cosmetic will have an exaggerated effect, as that price reduction will also affect reimbursement for BOTOX® therapeutic. Hr'g Tr. (Moatazedi) at 918:15-19. For example, if Allergan discounts its price for BOTOX® Cosmetic to compete with Jeuveau, it would impact Allergan not only by decreasing Allergan's profits for BOTOX® Cosmetic, but also by negatively affecting pricing and profits for BOTOX® therapeutic. *See* CX-0018C (Malackowski WS) at Q/A 156-57; *see also id.* at Q/A 56–57; Hr'g Tr. (Moatazedi) at 917:12-918:19.

Evolus has touted this pricing advantage over Allergan [ ] externally. For example, in one internal presentation, Evolus promoted its cosmetic-only strategy by stating that, "[

]." CX-2428.2 (Evolus Commercial Analysis). Publically, Evolus has maintained that its aesthetic-only indication gives it "tremendous pricing flexibility" compared to BOTOX® Cosmetic and other products with therapeutic indications. CX-2381C.9 (Evolus Investor Day); CX-0934 (Evolus S-1). Evolus additionally contends that it is not subject to other regulations to which companies with a therapeutic product, such as Allergan, are subject. For example, Evolus contends that it is not limited by the Physician Payments Sunshine Act and that it does not have to report payments it makes to

> doctors to the federal Open Payments database. Hr'g Tr. (Moatazedi) at 914:23-915:17. Evolus considers this a further advantage over its competitors, like Allergan, that are subject to these rules. *See* CX-1259 (Evolus Q3 2018 Earnings); CX-0934 (Evolus S-1).
>
> The bottom line is that Evolus has leveraged its cosmetic-only status to the detriment of Allergan by [
>
>]. For example, [
>
>], compared with Allergan's maximum offered discount of [ ] for BOTOX® Cosmetic. CX-2318C (Allergan Discounting); CX-2231C (Allergan list prices); CX-2416C (Evolus Account Pricing); *see also* Hr'g Tr. (Moatazedi) at 916:11-17. Evolus has further [
>
>]. CX-1706C (Knab Dep.) at 95:9-19; CX-2416C (Evolus Account Pricing Cheat Sheet). These [
>
>]. CX-0018C (Malackowski WS) at Q/A 165; CX-2604C.7 (Errata). Notably, as further evidence of Evolus's targeting of BOTOX® Cosmetic, Evolus [
>
>]. CX-0018C (Malackowski WS) at Q/A 165. Due to Jeuveau's deep discounting and pricing flexibility, and the significant losses Allergan would suffer if it were to lower prices for BOTOX®, Allergan cannot match Evolus on pricing.

Compls. Br. at 245–48 (footnotes omitted).

Respondents argue, in part:

> Complainants have not demonstrated that Jeuveau® undersells BOTOX®. As explained above, Allergan provides at least three discount programs (Allergan Partner Privileges, Brilliant Distinctions, and Allergan First), which make it difficult to evaluate the overall price differential between BOTOX® and Jeuveau®. RX-3158C.42-44, 62

> (Mulhern WS) at Q/A 229-37, 246-47, 355. It is undisputed, however, that Jeuveau®'s list price ($610) is higher than BOTOX® ($601) and, accordingly, this factor, if considered, weighs against a finding of substantial injury or is neutral. RX-3158.63 (Mulhern WS) at Q/A 357; *See Combination Locks* Comm'n Op. at 12.

Resps. Br. at 254–55.

The Staff argues, in part:

> Allergan's internal models indicate [
>
>]. *See* CX-2331C [ ]. For example, one of Allergan's [
>
>].
> *Id.* With over [ ] of BOTOX® Cosmetic sold in the United States per year, a price reduction of [ ] per vial would result in lost annual revenue to Allergan of more than [ ] just in terms of pricing. CX-0018C (Malackowski WS) at ¶ 181. And not only would a decrease in the price of BOTOX® Cosmetic affect Allergan's revenues for BOTOX® Cosmetic, it would affect revenue for BOTOX® therapeutic due to the way CMS calculates ASP for reimbursements, as described above. *Id.*

Staff Br. at 143.

The evidence shows that Evolus aggressively prices Jeuveau® to physicians [

]. CX-0018C (Malackowski WS) at Q/A 177; CX-1708C (Jafar Dep. Tr.) at 62–63; CX-0009C (McKenna WS) at Q/A 61. Evolus prices Jeuveau® [

]. That is, if Allergan reduces the price of BOTOX® Cosmetic, [

]. CX-2419C (Evolus Board Slides); CX-1705C (Moatazedi Dep. Tr.) at 193–94.

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Evolus has pricing flexibility in part because Jeuveau® is approved for only a cosmetic indication. *See* CX-0018C (Malackowski WS) at Q/A 156–57. Allergan does not have such flexibility to price BOTOX® Cosmetic, because BOTOX® is also approved for therapeutic indications. Allergan's ability to discount BOTOX® products is constrained due to the Centers for Medicare & Medicaid Services' ("CMS") regulations, which limit the amount reimbursed by CMS based on a weighted average sales price (ASP) that considers all ASPs for a product, including prices for different indications and vial sizes. *Id.*; CX-0009C (McKenna WS) at Q/A 62. These regulations require that a price reduction for BOTOX® Cosmetic will also reduce reimbursement for BOTOX® therapeutic. CX-0018C at Q/A 156–57.

Inasmuch as Jeuveau® is not approved for any therapeutic indications, its pricing is not constrained by CMS reimbursement. The evidence demonstrates that Evolus has touted this advantage over Allergan to Evolus investors. *See* CX-2381C.9 (Evolus Investor Day) (stating Jeuveau®'s aesthetic-only indication gives it "tremendous pricing flexibility" compared to BOTOX® Cosmetic and other products with therapeutic indications). The evidence shows that Evolus is aware of Allergan's constraints. CX-2428.2 (Evolus Commercial Analysis) [

]. The evidence demonstrates that the [ ] incentivizes physicians to administer Jeuveau®, rather than BOTOX® Cosmetic, to patients inasmuch as physicians can [

]. Evolus additionally argues that it is not subject to

other regulations to which companies with a therapeutic product, such as Allergan, are subject. Evolus acknowledges to its investors that it has the advantage of not being limited by regulations such as the Physician Payments Sunshine Act and that it does not have to report payments it makes to doctors to the federal Open Payments database. Evolus considers this an advantage over its competitors, like Allergan, that are subject to these rules. *See* CX-1259.8 (Evolus Q3 2018 Earnings Call) ("we don't believe that rules like Sunshine laws apply to Evolus"); CX-0934.112–.113 (Evolus SEC S-1); Moatazedi Tr. 915.

Moreover, Evolus has offered [ ] discounts that, [ ] discount on the price of Jeuveau®. CX-0018C (Malackowski WS) at Q/A 165; Moatazedi Tr. 917 (agreeing that the ASP for Jeuveau® is approximately [ ] per 100-unit vial, as compared to its list price of $610 per vial). For example, [ ].[26] CX-2318C (Allergan Discounting); CX-2231C (Allergan list prices); CX-2416C (Evolus Account Pricing Cheat Sheet). Evolus has further offered [ ].[27] CX-1706C (Knab Dep. Tr.) at 95;

[26] The list price for a 100U vial of BOTOX Cosmetic is $601 and $331 for a 50U vial. CX-2231C (Allergan product pricing list); CX-0009C (McKenna WS) at Q/A 58. The list price for a 100U vial of Jeuveau® is $610. RX-3162C (Moatazedi WS) at Q/A 34.

[27] [ ]. CX-0018C (Malackowski WS) at Q/A 166.

CX-2416C. In addition, Evolus offers [

]. CX-0018C at Q/A 165.

Over the long term, Evolus's aggressive pricing of Jeuveau® will erode Allergan's profitability for both BOTOX® Cosmetic and BOTOX® therapeutic. Inasmuch as Evolus [

], there is strong likelihood that Allergan will need to lower its pricing for its BOTOX® products in order to compete. CX-0018C (Malackowski WS) at Q/A 183–84; CX-0009C (McKenna WS) at Q/A 64–65. Allergan's internal models indicate [

]. CX-0018C (Malackowski WS) at Q/A 181. As noted above, a decrease in the price of BOTOX® Cosmetic affects Allergan's revenues for BOTOX® Cosmetic and revenue for BOTOX® therapeutic due to the way CMS calculates ASP for reimbursements. *Id*.

The administrative law judge thus finds that Daewoong has used the trade secrets at issue in this investigation thereby causing injury to Allergan. *See Rubber Resins*, Comm'n Op. at 10 (*citing Sausage Casings*, ID at 361).

3. Threat of Future Injury to BOTOX®

Complainants argue, in part:

> In addition to having caused substantial injury to the domestic industry, the continued importation and sale of Jeuveau poses a threat of continuing substantial injury to the domestic industry. Indeed, all relevant factors demonstrate a threat of substantial injury to the Domestic Industry Products: (1) substantial foreign manufacturing capacity; (2)

> explicit intention to enter into the U.S. market; (3) ability of the imported product to undersell the domestic product; (4) the inability of the domestic industry to compete with the foreign products because of vastly lower foreign costs of production and lower prices; and (5) the significant negative impact this would have on the domestic industry. *Rubber Resins Comm'n Op.* at 64.
>
> The Commission has repeatedly held that "[w]here unfair methods and acts have resulted in conceivable loss of sales, a tendency to substantially injure such industry has been established." *Railway Wheels ID* at 82 (quoting *Electric Power Tools ID* at 248–49). Here, because it is undisputed that Complainants have already lost sales and customers to Jeuveau (*see supra* Section VI.C.2.ii), a threat to substantially injure the domestic industry has been established.

Compls. Br. at 253.

Respondents argue, in part:

> Complainants' prediction that Jeuveau® may substantially injure BOTOX® in the future is speculative, unquantified, and unsubstantiated. To start, almost all of Allergan's domestic BOTOX® activity, including activities relating to BOTOX® Therapeutic, manufacturing of BOTOX® API for foreign sale, and R&D, cannot be injured by Jeuveau® at all. Complainants' attribution of likely harm to the BOTOX® Cosmetic market flies in the face of BOTOX®'s continued market dominance, growing sales, and increasing revenues. Complainants and Staff also ignore the many competitors poised to enter the market in the next few years, including one — Revance's Daxi — that [ ] third-party sources have identified as the likely #2 player in the market within months of its estimated 2020 launch. RX-3158C.35-36 (Mulhern WS) at Q/A 199-200. Mr. Malackowski's failure to grapple at all with this complicated competitive picture makes his analysis about future impact undeserving of being credited, and lead him to greatly overstate the likelihood and magnitude of any future harm to BOTOX® Cosmetic.

Resps. Br. at 256.

Even if there is no current injury, the Commission may "mak[e] a separate inquiry in this case with respect to the likelihood of future injury." *Corning Glass Works v. U.S. Int'l Trade Comm'n*, 799 F.2d 1559, 1567 (Fed. Cir. 1986); *accord Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1487 (Fed. Cir. 1986) (injury showing can include "prediction of the future effect of [Respondent's] unfair imports on the domestic industry"). Complainants can satisfy the "threat" of injury requirement "[w]hen an assessment of the market in the presence of the accused imported products demonstrates relevant conditions or circumstances from which probable future injury can be inferred." *Railway Wheels*, Unreviewed ID at 81–82 (quoting *Electric Power Tools*, Unreviewed ID at 248). Factors considered in making such an assessment include, among other things:

> (1) substantial foreign manufacturing capacity; (2) ability of imported product to undersell the domestic product; (3) explicit intention to enter into the U.S. market; (4) the inability of the domestic industry to compete with the foreign products because of vastly lower foreign costs of production and lower prices; and (5) the significant negative impact this would have on the domestic industry.

Certain Rubber Resins and Processes for Manufacturing Same, Inv. No. 337-TA-849, Comm'n Op. at 64 (Feb. 26, 2014).

a) Substantial Foreign Manufacturing Capacity

Complainants argue, in part:

> Daewoong stated in a press release that its second manufacturing facility was Korean GMP certified and, in combination with its first factory, Daewoong was able to manufacture over 5 million vials of Nabota (the Korean DWP-450 product) annually—with, if needed, an extended capacity of 9 million vials per year. CX-1245.1 (Daewoong Press Release). Daewoong's corporate representative on the issue (Kyoung Yun Kim), in fact, agreed that "Daewoong has substantial manufacturing capacity in Korea permitting it to manufacture Jeuveau for importation and sale into the

> United States." CX-2536C (KY Kim Dep.) at 155:22-156:4. Thus, Evolus will be able to meet the demand for Jeuveau, regardless of how high its market share climbs and despite continued growth in the BTX market. And Evolus shares Daewoong's opinion that there is sufficient manufacturing capacity to meet expected U.S. demand for Jeuveau. *See* CX-1705C (Moatazedi Dep.) at 90:15-91:5; CX-1704C (Sabad Dep.) at 165:9-17 (testifying that Daewoong's manufacturing capacity was as high as six million vials per year); CX-2234.11 (Q1 Earnings Call); *see also* Hr'g Tr. (Mulhern) at 933:3-14.

Compls. Br. at 253–54.

Respondents argue, in part:

> Although Daewoong has foreign capacity to produce Nabota® and Jeuveau®, that is not dispositive of the issue. *Combination Locks,* Comm'n Op. at 11 ("[E]vidence of foreign capacity even if coupled with a large U.S. market does not show a tendency to injure *absent a strong showing that foreign manufacturers intend to direct their capacity toward penetrating the U.S. market*."). (emphasis added). Nabota® and Jeuveau® are sold around the world—for example Jeuveau® is sold as Nuceiva® in Canada and Europe—and Daewoong could not simply neglect its obligations in other markets and devote 100% of its capacity to the U.S. RX-3167C.26, 27 (Kyoung Yun KIM WS) at Q/A 16, 20. Daewoong's capacity to manufacture Nabota® and Jeuveau®/Nuceiva® is not even relevant to this inquiry, and this factor is neutral.

Resps. Br. at 257.

The evidence demonstrates that Daewoong has more than sufficient foreign manufacturing capacity to supply the domestic demand for Jeuveau® (and indeed the entire U.S. BTX cosmetic market). The total U.S. market for cosmetic BTX products in 2019 was 2.3 million units, which is far less than the [ ] unit manufacturing capacity of the new building in Korea that Daewoong built to supply the U.S. market and other markets with DWP-450 (*i.e.*, Jeuveau®). CX-1245.1 (Daewoong Press Release).

b) Explicit Intention to Enter into the U.S. Market

Complainants argue, in part:

> As explained above, Evolus has already entered the market with Jeuveau with the specific intent of targeting Allergan. *See supra* Section VI.C.2.i. Indeed, Jeuveau directly competes with BOTOX® Cosmetic. Respondents sell and distribute Jeuveau using the same channels that Allergan uses to sell and distribute BOTOX® Cosmetic and have targeted BOTOX® Cosmetic by highlighting Jeuveau's 900 kDa molecular weight (and associated benefits). *See id.*

Compls. Br. at 254.

Respondents argue, in part:

> Complainants' expert Mr. Malackowski treats the cosmetic toxin market as a two-player, zero-sum game, with Jeuveau® capturing all or nearly all of its sales from BOTOX® Cosmetic. This simplistic picture of the market is counterfactual. Mr. Malackowski largely ignores competition with Dysport and Xeomin (the other current competitors); market expansion; and the entrance of new, major competitors, rendering his analysis fundamentally unreliable.
>
> As discussed above, data from Allergan, Evolus, and surveys conducted by third parties demonstrate that "[m]ost of Jeaveau's overall market share gains have come largely from Dysport and XEOMIN, with BOTOX® relatively unaffected." RX-3561.3 (RBC Capital Markets - Deep dive into BOTOX®); RX-3158C.33-35 (Mulhern WS) at Q/A 184-195. Complainants provide no reason to believe this will change.
>
> As for market expansion, Allergan projects that the facial injectable market may [ ]; its sales are expected to increase each year going forward by [ ] or more. RX-0552C.15 (Allergan Corporate Overview Presentation). A substantial amount of this market-wide growth will be attributable to Evolus' marketing efforts in "actively building out the Jeuveau® brand with the 'youngest generation' contemplating aesthetic neurotoxin treatments." RX-3162.8 (Moatazedi WS), at Q/A 46. Allergan itself has described competition with Jeuveau®

> "[
>]." RX-0552C.13 (Allergan Corporate Overview Presentation) (emphasis added). Allergan's CEO, Brent Saunders, explained that "the fact that there will be four or five potential neuromodulators on the market in the U.S. ***is probably a good thing*** for the overall market because our penetration in this market is in the single-digits. This market should expand significantly." RX-0569.2 (Allergan CEO BOTOX® Is in a Very Strong Position) (emphasis added).
>
> Mr. Malackowski also completely ignores the additional competitors due to enter the market. RDX-0001C.10 (Mulhern Demonstrative); CX-2334C [
>], at tab 'Botox Cx.' Mr. Malackowski's failure to discuss *any* of these competitive launches is conspicuous, given [
>]. For example, Allergan's [
>
>]. Hearing Tr. 935:15-936:15. During this same period [
>
>]. Consistent with these projections, the January 2020 RBC Capital Markets survey discussed above found that "DAXI entry was viewed as the bigger competitive threat [than Jeuveau®]. . . Those surveyed saw a meaningful 26 percent share going to DAXI as the clear number 2 in the market." RX-3561.1 (RBC Capital Markets - Deep dive into BOTOX®). *See also* Hearing Tr. 935:25-936:7.
>
> Daxi and the other new competitors may take more sales from BOTOX® than Jeuveau®, and Jeuveau® may take some of its sales from these new competitors. Mr. Malackowski's decision not to take this into account at all in his analysis reveals that his prediction of future injury is a conclusion in search of evidence rather than the other way around. Because the full record about the cosmetic toxin market shows that Jeuveau®'s impact on BOTOX® Cosmetic will be modest, at best, this factors weighs against a finding of a threat of substantial injury.

Resps. Br. at 258–59.

As discussed above, the evidence shows that Evolus has already entered the market with Jeuveau® with the specific intent of targeting Allergan. Indeed, Jeuveau® directly competes with BOTOX® Cosmetic. Respondents sell and distribute Jeuveau® using the same channels that Allergan uses to sell and distribute BOTOX® Cosmetic.

c) Ability of the Imported Product to Undersell the Domestic Industry Products

Complainants argue, in part:

> As explained above, Jeuveau has the ability to undersell the Domestic Industry Products, [ ]. *See supra* Section VI.C.2.iii. Respondents will continue being able to undersell BOTOX® in the future, in part due to the pricing flexibility from being a cosmetic-only product. *See id.* The evidence shows that Respondents will additionally enjoy pricing advantages with respect to MT10109L. Although Allergan [ ], it already expects [ ]. *See* CX-0009C (McKenna WS) at Q/A 96.

Compls. Br. at 255.

Respondents argue, in part:

> Complainants and Staff ignore the fact that the cost of manufacturing a 100-unit vial of Jeuveau® is nearly [ ] than the cost of producing the equivalent of imported BOTOX®. RX-3158C.34-35 (Mulhern WS) at Q/A 177-83. [ ] Jeuveau® relative to BOTOX® weighs against any inference of risk of future substantial injury to any alleged BOTOX® domestic industry. *See, e.g., Rubber Resins*, Comm'n Op. at 64.

Resps. Br. at 259–60.

The evidence shows that with Jeuveau®, respondents have the ability to undersell BOTOX®. Respondents will continue to be able to undersell BOTOX® in the future, in

part due to the pricing flexibility from Jeuveau® being a cosmetic-only product. *See* CX-0018C (Malackowski WS) at Q/A 156–57.

d) Significant Negative Impact the Imported Product Would Have on the Domestic Industry

Complainants argue, in part:

> Evolus projects that Jeuveau will reach [ ] U.S. market share in its first year following launch (*i.e.*, by May 2020). CX-0018C (Malackowski WS) at Q/A 124; CX-2604C.4 (Errata); CX-2430C.16 (Evolus June Forecast); Hr'g Tr. (Moatazedi) at 905:11-906:5. Similarly, according to an Evolus pricing sensitivity analysis, [ ]. CX-0018C.45 (Malackowski WS) at Q/A at 127; CX-2604C.5 (Errata); CX-2385C (Pricing Analysis). These market shares translate into [ ]. For example, according to internal documents and the testimony of Evolus's CEO, Evolus projects its revenue and sales for Jeuveau [ ]. CX-1705C (Moatazedi Dep.) at 160:16-162:15 (confirming projections from an internal investor relations update).
>
> Daewoong's projections for Jeuveau are consistent with Evolus's. For example, according to a December 3, 2018, Daewoong analysis, Daewoong estimated that Jeuveau would achieve and maintain a long term U.S. market share [ ]. CX-2175C (Nabota Business Plan). Moreover, an internal Daewoong email summarizing a September 7, 2018 meeting between Daewoong personnel and Evolus "c-suite executives" reveals that [ ]. CX-0843C.7 (email from Seong Soo Park); CX-0844C.4 (email attachment); CX-0018C (Malackowski WS) at Q/A 125; CX-2604C.5 (Errata).
>
> Third-party industry analysts likewise forecast around a 20 percent domestic market share for Jeuveau. For

example, as of May 2, 2019, the "consensus" among third-party analysts was that Jeuveau would achieve up to 18 percent market share in the United States, with BOTOX® Cosmetic's market share decreasing from 75 percent to 63 percent. CX-2413C.13 (Evolus Investor Relations Update). One analyst, H.C. Wainwright, forecast that Jeuveau would achieve 21 percent market share by 2022, and Cantor Fitzgerald forecast a 20 percent market share by 2022. *Id*. Thus, a conservative but realistic estimate—based on Evolus's, Daewoong's, and third-party analysts' projections—is a 20 percent U.S. market share for Jeuveau.

Although all of Jeuveau's growth will not necessarily be at the expense of BOTOX® Cosmetic (as it was immediately following Jeuveau's release), the evidence shows that at least [ ] market share likely will come at the expense of BOTOX® Cosmetic, resulting in [ ] market share loss for BOTOX® Cosmetic. CX-0018C (Malackowski WS) at Q/A 129-132; CX-2604C.5 (Errata). Indeed, the Guidepoint market share data through the end of 2019 [ ] of Jeuveau's market share has come at the expense of BOTOX® Cosmetic. *See supra* Section VI.C.2.ii.

This is consistent [ ] third parties' projections. For example, a 2017 study regarding the U.S. BTX market commissioned by Evolus determined that, [ ] percent of Jeuveau's market share would come from BOTOX® Cosmetic. CX-2384C (Neurotoxin Quantitative Research); CX-0018C (Malackowski WS) at Q/A 131; CX-2604C.5 (Errata). Similarly, an internal pricing sensitivity analysis performed by Evolus showed that, [

]. CX-2385C (Pricing Analysis); CX-0018C (Malackowski WS) at Q/A 132; CX-2604C.5 (Errata). [ ] third party estimates, of BOTOX® Cosmetic's market share loss due to Jeuveau are consistent. *See* CX-0018C (Malackowski WS) at Q/A 133; CX-2604C.5

> (Errata); CX-2333C (Allergan Evaluation); CX-2270 (Wall Street Journal article); CX-2298C (Cantor Fitzgerald Report); CX-2300C (RBC Capital Markets Report); CX-2301C (Piper Jaffray Report).
>
> As Mr. Malackowski explains, a [ ] percentage point decrease represents a *yearly loss to Allergan of more than* [ ] *in profit*. CX-0018C (Malackowski WS) at Q/A 139-140 Indeed, these calculations are conservative and do not account for future expected growth in the U.S. market for cosmetic BTX products; as the market expands, a single percentage point loss of market share represents an even larger loss of profits to Allergan. *Id*. at Q/A 141. Such a loss—[ ] per year—is substantially injurious by any measure.
>
> . . .
>
> Allergan's internal models, [
>
>]. *See* CX-2331C [ ]. For example, one of Allergan's [
>
>]. *Id.* With over [ ] of BOTOX® Cosmetic sold in the United States per year, a price reduction of [ ] per vial would result in lost annual revenue to Allergan of more than [ ] just based on decreased prices. *See* CX-0018C (Malackowski WS) at Q/A 181; CX-2604C.9 (Errata). And not only would a decrease in the price of BOTOX® Cosmetic affect Allergan's revenues for BOTOX® Cosmetic, it would affect revenue for BOTOX® therapeutic due to the way CMS calculates ASP for reimbursements, as described above. *Id.*

Compls. Br. at 260–64.

Respondents argue, in part:

> All sales of Jeuveau® have taken place after the filing of the Complaint, and Complainants have not alleged any diminution of production, profitability, or sales to BOTOX®, to date. As discussed above, based on Allergan's 2019 financials, Allergan's [
>
>].
>
> In November 2019, Respondents' expert Ms. Mulhern performed an assessment of the possible upper

bounds of injury to BOTOX® that could be attributed to Jeuveau®. RDX-0001C.15 (Mulhern Demonstrative); *See* fn 52. RX-3158C.54-55 (Mulhern WS) at Q/A 314-323. She started by correcting certain flaws in Mr. Malackowski's analysis (for example, correcting his clearly incorrect assumption that *all* of Jeuveau®'s sales came at the expense of BOTOX®). But she deliberately did not take into account the extent to which BOTOX® has benefitted from Evolus' overall expansion of the marketplace (which could serve to offset, to some extent at least, any lost sales). *Id*. And yet even under this likely overstated estimate of harm, the upper bound of potential future injury caused by Jeuveau® was no more than [ ] percent of estimated worldwide BOTOX® revenues, [ ] percent of worldwide BOTOX® Cosmetic revenues, and [ ] percent of U.S. total BOTOX® revenues. *Id*. In a different context, [

].
Id. at 55. Similarly, the Commission has previously rejected this level of lost sales as not substantial. *Combination Locks*, Comm'n Op. at 9-12. Recently reported 2019 sales information for Evolus indicates that it failed to achieve its 2019 sales projections, which suggests that the estimated potential lost BOTOX® revenue calculated in the above-described demonstrative is even more overstated.

. . .

Complainants and Respondents agree that the substantiality of any threat of future injury must be evaluated with respect to Complainants' entire domestic industry, *i.e.*, MT10109L, BOTOX® Cosmetic, and BOTOX® Therapeutic, rather than piecemeal. RX-3158C.50 (Mulhern WS) at Q/A 287; CX-0018C.49 (Malackowski WS) at Q/A 143. Even to the extent that Jeuveau® is found to pose a small threat of future injury to one sector of Complainants' domestic industry, that is not dispositive. Indeed, as explained *supra*, Complainants have not shown a likelihood of *any* harm to MT10109L or BOTOX® Therapeutic. These constitute more than half of Complainants' alleged domestic industry. RX-3158.26 (Mulhern WS) at Q/A 152; RX-3148C (Mulhern Exhibit 14); RX-2334C [

], at tab 'Botox Cx.' As for the other smaller portion, the record will show that BOTOX® Cosmetic is the only product from

> Complainants that Jeuveau® will compete with before the Target Date. Of that small portion, the record shows that approximately [ ] the domestic investments in manufacturing pertain to foreign sales of BOTOX® Cosmetic, which cannot be injured by domestic sales of Jeuveau®. dx-0001C.8 (Mulhern Demonstrative); RX-3143 (Mulhern Exhibit 10); RX-0556.5 (Allergan 10-K 2013); RX-0557.4, 46 (Allergan 2014 10-K); RX-0559.59, 73 (Allergan 10-K 2016); RX-0569.60, 64 (Allergan 10-K 2017); RX-0561.54, 60 (Allergan 2018 10-K); RX-0562.65, 71 (Allergan 10-Q, June 30, 2019); (CX-2251 (Units Manufactured of Botox C and Therapeutic (including HH) for 2014-2018). And the threat to U.S. sales of BOTOX® Cosmetic is *de minimis*, particularly in view of Allergan's dominant market share. RX-3158.32-32 (Mulhern WS) at Q/A 168.
>
> When these three sets of investments are taken together, the reliable and non-speculative record makes clear that only a small section of Complainants' alleged domestic industry could possibly be threatened by Jeuveau®. That threat is not substantial. Complainants have therefore not met their burden of showing that there is a likelihood of substantial threatened injury to their alleged domestic industry.

Resps. Br. at 260–62.

The evidence shows that Jeuveau® has already achieved a 7.5% market share, with the vast majority coming from BOTOX® Cosmetic. Moreover, Evolus has repeatedly stated that it is confident Jeuveau® will achieve the number two U.S. market position within 24 months of launch. *See* CX-1179.1 (Evolus Press Release) (Evolus announcing that Jeuveau® attained the number three market position in the United States BTX market within "90 days of launch . . . ahead of expectations," and Evolus "remain[s] highly confident in [its] ability to achieve the number two U.S. market position within 24 months of launch"); CX-2429C.16 (Evolus June Forecast); CX-1260.7-8 (Q2 Earnings Call); CX-2617.1-2 (Evolus Press Release). Mr. Moatazedi reiterated at the Hearing that

Evolus continues to expect to achieve the number two U.S. market position. *See* Moatazedi Tr. 906–907. With [ ] of Jeuveau®'s market share coming at the expense of BOTOX® Cosmetic, the evidence demonstrates that this will result in over [ ] in yearly lost profits to Allergan.

The evidence further shows that Allergan also faces potential long-term price erosion due to Jeuveau®. As explained by Mr. Malackowski, [

], this puts pressure on Allergan to lower its pricing for its BOTOX® products to compete. CX-0018C (Malackowski WS) at Q/A 183-84; CX-2604C.9 (Errata); CX-0009C (McKenna WS) at Q/A 64-65. If this occurred, over the long term, it would impact Allergan's ASP for CMS reimbursement purposes, resulting in a significant amount of lost revenue for Allergan, even for BOTOX® therapeutic. *Id.*

4. Threat of Future Injury to MT10109L

Complainants argue, in part:

> Evolus's actions, including its Jeuveau discount and pricing strategy, will also significantly impact MT10109L. Even though MT10109L is not yet being sold commercially and Allergan [ ], Allergan [
>]. CX-0009C (McKenna WS) at Q/A 96, 100. In other words, Evolus's discounting for Jeuveau will likely [
>
>]. CX-0018C (Malackowski WS) at Q/A 182; CX-0009C (McKenna WS) at Q/A 64-68, 89-90, 93, 95-96, 100. In that event, Allergan would [
>]. *See id.*

> MT10109L will further be injured by Jeuveau's head start advantage, an advantage gained by reason of Respondents' trade secret misappropriation. Complainants expect MT10109L to receive FDA approval and launch in the United States around [ ]. There is significant demand for BTX products and specifically for BTX products approved for the treatment of glabellar lines. By securing a strong foothold in the BTX market now with a 900 kDa BTX product, Respondents will have existing customers (doctors and patients) who may not want to change their BTX product when MT10109L launches. CX-0009C (McKenna WS) at Q/A 98–99. Jeuveau will occupy market share to the detriment of MT10109L, resulting in additional lost future sales and profits for Complainants. *See id.* This is because Jeuveau is being marketed and sold to customers who may otherwise be future customers of MT10109L. *Id.* Indeed, just as customers who switched to Jeuveau as a result of the J.E.T. program may not return to BOTOX® Cosmetic, they may similarly not switch from Jeuveau to MT10109L. As Colleen McKenna explained, physicians generally stock only a few different neurotoxin products, and, if Jeuveau remains on the market, physicians may not stock MT10109L at all when it enters the market. *Id.* Thus, Complainants will suffer lost market share and profit for MT10109L as a result of Jeuveau. The reality is that, but for Respondents' unfair acts, when MT10109L is approved, there would have been no known third party 900 kDA BTX products in the United States competing with MT10109L.

Compls. Br. at 264–65.

Respondents argue, in part:

> As discussed in more detail *supra* at II.B.1., Complainants hope that MT10109L will be approved by the FDA at some point in [ ]. CX-2010C.12 (Joint Steering Committee Presentation, November 2018). Some Allergan [ ]. RX-3003C.81 (Schultes Dep. Desg. at 81:15-23). Indeed, at the evidentiary hearing, Allergan's Senior Vice President of Pharmaceutical Development, Dr. Sesha Neervannan, [ ]. Hearing Tr. 449:19-450:23.

MT10109L was [

]. CX-1998C.9 (Joint Steering Committee Presentation, February 2014); CX-1999C.13 (Joint Steering Committee Presentation, June 2014); RX-1657C.24 (Joint Steering Committee Presentation, December 2014); Hearing Tr. 449:19-450:23. This did not come to pass — far from it. Allergan's documents show that the projected approval and launch dates for MT10109L[

]. *See supra* at II.G.2.

Complainants' documents reveal a number of explanations [

]. RX-0078C.2 [

]; RX-00548C.2 [

]; CX-2002C (JSC Meeting Minutes, dated March 11-12, 2015). Even after MT10109L finally went into clinical trials in 2018 [ ], Allergan executives, [

]. RX-1690 (Korea Biomedical Review article, May 27, 2019); RX-0742C.1 (Allergan email from Pasha Sateri to Colleen McKenna and Carrie Strom on 5/30/2019).

Adding even further uncertainty to MT10109L's prospects, Medytox is currently under criminal investigation based on fabrication of manufacturing records and improper use of experimental drug substances that had not been approved by the KFDA. *See* Hearing Tr. 325:5-326:8. As of February 19, 2020, a well-known Korean media outlet reported that Korean prosecutors have indicted Medytox's head of manufacturing; that Medytox is facing additional charges of fabricating testing results; and that Medytox CEO JUNG is a target of the investigation. *See* https://n.news.naver.com/article/056/0010793780. At a minimum, these facts further complicate the already-speculative estimate that MT10109L will be in the market by [ ].

It is self-evident that there can be no *actual* substantial injury to MT10109L, as there is no product yet available for sale that could even theoretically be injured. RX-3003C.81 (Charles Schultes Dep. Desg. At 81:15-23). There are no sales of MT10109L to be lost to Jeuveau® (or to anyone else, for that matter); there are no MT10109L prices that could be undercut; there are no profits from MT10109L that could be impacted. *See, e.g.*, RX-3158.17 (Mulhern WS) at Q/A 84. Allergan [

]. RX-2934.12 (Allergan's Responses to Daewoong's First Set of RFAs) at No. 13; RX-2382.12 (Citi Global Healthcare Conference Transcript); RX-2967C.6 (Medytox's Responses to Daewoong's Third RFAs), No. 25. And Complainants do not allege [

]. CX-2350C (Allergan's Total BOTOX® Related Projects R&D Cost); CX-0018C.36 (Malackowski WS) at Q/A 100.

Since it is impossible to predict whether and when (if ever) MT10109L will launch, it is equally impossible to predict a substantial threat of *future* injury. Complainants' speculative, unsupported, and self-serving testimony of potential injury to MT10109L does not satisfy their burden. For example, Mr. Malackowski admits that Allergan [

]. CX-0018C.49 (Malackowski WS) at Q/A 142. Mr. Malackowski further speculates, again without any documentary support, that Allergan "[

]." *Id.* (emphasis added). This is pure speculation, which cannot be credited. *See, e.g., Activity Tracking Devices* at 77-79 (finding that "[Complainants' expert] fails to provide any concrete projections regarding [Respondent] sales or [Complainants'] lost sales, and any opinion regarding future injury is thus merely speculation.").

> The Commission has never found a threat of substantial future injury to a product that is still years away from a possible launch under even the most favorable of estimates. It should not start now.

Resps. Br. at 247–49 (footnote omitted).

The Staff argues, in part:

> No party presented sufficient reliable evidence regarding MT10109L in order for the ALJ or the Commission to properly assess whether the importation of the accused products have the effect of threatening to substantially injure sales of MT10109L in the future.

Staff Br. at 143.

The evidence shows that MT10109L is currently undergoing phase III clinical trials in the United States and is not yet FDA approved for marketing and sale in the United States. Even under complainants' most optimistic estimates, MT10109L is not expected to be marketed and sold in the United States until [ ]. CX-0009C (McKenna WS) at Q/A 97.

MT10109L, like BOTOX® and Jeuveau®, is a 900 kDa BoNT type A product. BOTOX® and Jeuveau® are both sold in vials containing the drug in powder form and need to be reconstituted (solubilized) in saline solution in order to be administered by injection into the patient. MT10109L, on the other hand, is a solubilized product that can be administered directly into a patient. Thus, with MT10109L, there is no need for reconstitution with saline prior to administration. There are considerations, both known and yet unforeseen, that factor into the market's acceptance of MT10109L (or any other yet-to-be marketed product) in the future.

Thus, unlike the overwhelming evidence that the sales of Jeuveau® are having a direct and detrimental effect on the sales of and profits from BOTOX®, complainants

have not provided sufficient evidence of such direct effect or likely effect caused by Jeuveau® again MT10109L. The administrative law judge finds that the evidence does not demonstrate that the importation of the accused products have the effect of threatening to substantially injure sales of MT10109L in the future.

IX. Respondents' Affirmative Defenses

A. Statute of Limitations

Respondents argue, in part:

> Complainants' claims are time-barred because they accrued more than three years before January 25, 2019, when Complainants filed the Complaint.
>
> . . .
>
> The Federal Circuit has held that "claims for trade secret misappropriation accrue for statute-of-limitations purposes when the plaintiff knew or reasonably should have known of the facts that give rise to the claim." *Raytheon Co. v. Indigo Systems Corp.*, 688 F.3d 1311, 1316 (Fed. Cir. 2012). The evidence shows that Complainants knew or should have known about the acts that allegedly underlie their misappropriation claims as early as April 2015 and no later than December 2015, *i.e.*, more than three years prior to filing its ITC Complaint in January 2019.
>
> . . .
>
> Complainants' strain misappropriation claim is time-barred because Complainants were or should have been aware that Daewoong possessed a strain they allege was misappropriated since at least 2014. Indeed, Medytox admits it first suspected Daewoong had misappropriated its strain by April 2015.
>
> Medytox admits that [
>
>]. CX-2573.52 (Compl.'s Responses to Resp's First Set of ROGs) at No. 33. Daewoong's U.S. Patent 9,512,418 ("the '418 patent"), CX-1727 (U.S. Patent 9,512,418), describes experiments comparing the effects of Allergan's BTX-A1 (Botox®) and

Daewoong's BTX-A2 (DWP-450) and identifies the *C. botulinum* strain used to produce each as "Wild-type hall." *See e.g.*, RX-3330.12 (U.S. Patent 9,512,418). Similarly, in October 2014, Daewoong deposited the DNA sequence for the toxin gene cluster for its *C. botulinum* strain into GenBank, and identified it as "neurotoxin type A gene." *See* RX-1880.6 (Medytox Citizen Petition (2017)). Indeed, Medytox used the statements in the '418 patent and GenBank to allege to the FDA in its Citizen Petition that Daewoong's "DWP-450" strain "is the same unaltered Hall strain as used to produce Botox®," i.e., a Hall A-Hyper strain like Medytox's strain. RX-1880.8 (Medytox Citizen Petition (2017)). Thus, Medytox had actual knowledge of its claims by April 2014.

Based on these public disclosures in 2014, Complainants had constructive notice of the essential facts underlying their misappropriation allegations—that Daewoong allegedly had a Type A Hall strain isolated in Korea that was like Botox®'s strain and thus Medytox's strain. *See Advanced Cardiovascular Systems, Inc. v. Medtronic Vascular, Inc.,* 182 Fed. Appx, 994, 999 (Fed. Cir. 2006) (holding misappropriation claims were time-barred due to defendant's "constructive knowledge" arising from a European patent application, publications, and disclosures at conferences that both plaintiff and defendant attended); *Informatics Applications Group, Inc. v. Skholnikov*, 836 F. Supp. 2d 400, 442 (E.D. Va. 2011) (claim time-barred where plaintiff "had at least constructive notice that its trade secrets had been included in the patent documents … more than three years before … suit was filed.").

Furthermore, even assuming that Medytox's knowledge of Daewoong's patents as of 2014 did not trigger the limitations period, Medytox admitted that it suspected Daewoong of misappropriating its strain by April 2015, more than three years before the Complaint was filed in January 2019. In his witness statement, Medytox's CEO, Hyun Ho JUNG, admitted that he first became suspicious that Daewoong had misappropriated Medytox's Hall A-hyper strain at a conference in Dubai in April 2015. CX-0013C.61 (Hyung Ho JUNG WS) at Q/A 113-115 ("Q. When did you first become suspicious that Daewoong had misappropriated Medytox's Hall A-hyper strain? A. In April 2015, [when] I attended a botulinum toxin conference in

Dubai[.]"); CX-0667C.1 (Snapshots of Daewoong's 2015 Slides). Dr. JUNG stated that his suspicions were based on Daewoong's presentation, which described Daewoong's strain as a "wild-type Hall-A strain"—the same information that was earlier disclosed in Daewoong's '418 patent. *Id.* at Q/A 113; CX-0667C.1 (Daewoong Presentation Slides).

In addition, according to an internal Medytox document describing the chronology of its efforts to investigate the purported theft of its strain, Medytox began affirmatively scrutinizing the origin of Daewoong's strain following the April 2015 conference in Dubai, including demanding to have a "discussion session" with Daewoong on July 29, 2015. RX-1790C.6-7 (Korean litigation summary of criminal action).

. . .

At the hearing, Dr. JUNG testified that he confronted Daewoong's representatives about the origin of Daewoong's strain at the April 2015 conference. Hearing Tr. 334:3-10 ("And then came the 2015 DOMA held in Dubai. So the folks from Daewoong made a certain representations that what they had come up -- come upon was a hyper strain. And I said hmm, that -- and I chose to speak with Daewoong, and for some reason, they were rather highbrowed."). Dr. JUNG also testified that it was at this conference that he became "dubious" about the Daewoong's strain; in fact he became so dubious that Medytox began discussing the issue with Allergan in December 2015. *See* Hearing Tr. 341:12-342:4 ("[I]t was I believe in 2015 at the Doma in Dubai that Daewoong started saying that – Daewoong said that their strain was first a hyper strain and that they had found it in the ground soil. And I was a little dubious about that…[W]e had this idea to bring this up during this discussion with Allergan that something like that had transpired, by way of -- by way of reporting."). That [

]. RX-1655C.4 (JSC Meeting Minutes, Dec. 15, 2015) [

]; *see also* Hearing Tr. 342:5-23. At the hearing, in response to questions by Staff, Dr. JUNG tried to place Medytox's suspicions in 2016, when he spoke to Respondents' witness Chung Sei KIM, which contradicted his testimony in his witness statement that Medytox began to suspect Daewoong

in 2015 (*supra*). *See* Hearing Tr. 337:4-7. Mr. Menchel then began to cross-examine Dr. JUNG to establish this inconsistency, but stopped his questioning when the ALJ commented that the JSC meeting minutes document "speaks for itself." Hearing Tr. 342:15-23.

Medytox's witness Dr. Gi Hyuk YANG similarly confirmed that Medytox had suspicions about Daewoong's strain, which it [
]. RX-1655C.4 ([ ] Dec 15, 2015)
[
]; RX-3015C.17-18 (Gi Hyuk YANG Dep. Desg. at 68:10-70:4, 71:11-22, 71:24-72:12).

. . .

Dr. YANG's testimony about the meeting with Allergan corroborates that Medytox was suspicious that Daewoong had misappropriated its strain by no later than December 2015, over three years before the Complaint was filed, and proves that both Medytox and Allergan were on notice of the potential misappropriation claim as of that time.

Indisputably, by December 2015 at the latest, Medytox was suspicious about the origin of Daewoong's strain and had sufficient information to make further inquiry. That is enough to trigger the statute of limitations. *See Phillip M. Adams & Associates, LLC v. Dell Computer Corp.*, 519 Fed. Appx. 998, 1007 (Fed. Cir. 2013) (The statutory discovery rule "does not allow plaintiffs to delay filing suit until they have ascertained every last detail of their claims… All that is required to trigger the statute of limitations is ... sufficient information to apprise the plaintiff of the underlying cause of action so as to put them on notice to make further inquiry if they harbor doubts or questions' about the defendant's actions.").

. . .

As early as 2014, Complainants also knew of the critical features of Daewoong's manufacturing process for DWP450 that they now allege were misappropriated as those features were disclosed and claimed in Daewoong's '418 patent. CX-2573.52 (Compl.'s Responses to Resp's First Set of ROGs) at No. 33. Specifically, Medytox's allegedly misappropriated process, including, *inter alia*, the three critical steps—[

>]—were all disclosed as part of Daewoong's process for producing DWP450 in Daewoong's '418 patent. *Compare* RX-3330.13 (US Patent 9,512,418) at claims 1 & 10, Fig. 1 *with* CX-0010C.51-53 (Pickett WS) at Q/A 255-259. Thus, since 2014, Medytox was actually aware (by virtue of its knowledge of Daewoong's '418 patent) and Allergan was at least constructively aware (by virtue of the patent's publication) of the "particularly important" facts undergirding its claim that its process was misappropriated by Daewoong; Complainants were constructively aware. *Advanced Cardiovascular Systems*, 182 Fed. Appx. at 999; *Informatics Applications Group,* 836 F. Supp. 2d at 442.
>
> In addition, Medytox has asserted that it "has always had safeguards in place to protect trade secrets against theft," and in 2007 went even further by monitoring employee emails and printings. *See* CX-0017C.46-47 (Seong Hun CHANG WS) at Q/A 9-11. Dr. JUNG testified that Medytox ran regular security checks to protect its confidential information and detect suspicious activity, which is how it discovered Dr. Lee's (allegedly) suspicious activities. RX-3019C.29 (Hyun Ho JUNG Dep. Desg. Vol. I) at 115:21-116:2. Given that Medytox already knew about Daewoong's patents in 2014, Medytox through "reasonable diligence" should have known about Dr. Lee's supposedly suspicious use of documents and email well before January 2016 (*i.e.*, the three years cut-off for the statute of limitations here). *Advanced Cardiovascular Systems*, 182 Fed. Appx. at 999. There are virtually no facts alleged in the Complaint concerning Medytox's process misappropriation claims that were not also available to Medytox in early 2014, more than four years prior to bringing this ITC action.

Resps. Br. at 265–77.

Complainants argue, in part:

> In any event, the Complaint was filed well within any conceivably applicable statute of limitations because it was filed just as triggering events were taking place – Respondents receiving FDA approval and the imminent commercial importation of DWP-450. The limitations period could not have begun, as Respondents contend, when Daewoong filed its patent application in 2014 or when Medytox's CEO heard a presentation describing

Daewoong's strain as a "type A" strain in 2015, even if that information was passed on to Allergan. *See* Resps. Prehr'g Br. at 194-98; RX-1655C.4 (Joint Steering Committee Minutes, 12/15/15). [

]. *See* Hr'g Tr. (HH Jung) at 343. For the same reason, Complainants' awareness of Evolus's U.S. clinical trials of DWP-450 did not start the clock. *See* Resps. Prehr'g Br. at 198-200; RX-3544C (Maltman Email, 07/26/14).

What the undisputed evidence does show is that – far from sitting on its rights – Medytox [

], *see* CX-0013C (HH Jung WS) at Q/A 124, through which Medytox learned several important facts. [

], *see* CX-0013C (HH Jung WS) at Q/A 137. Second, Chang Woo Suh attended the same university and worked in the same lab as BK Lee, a former Medytox employee. And finally, BK Lee had subsequently gone to work for Daewoong. *Id.*; *accord* RX-3159C (Suh WS) at Q/A 58-62. Further investigation by Medytox revealed that prior to leaving Medytox, BK Lee had printed and emailed himself highly sensitive company documents, which as discovery in this Investigation revealed, he still retained in 2019. *See, e.g.*, CX-2452C (BK Lee Email, 11/02/07); CX-2453C-59C (BK Lee Email Attachs., 11/02/07).

At that point, in March of 2017, Medytox appropriately pursued a government investigation of Daewoong – the most expeditious approach to fact finding in a country that lacks U.S.-style civil discovery. *See* Korean Criminal Case No. 2017-000236; CX-1832 (Decision in Korean Criminal Case); CX-0013C (HH Jung WS) at Q/A 138. This approach demonstrates diligence, the opposite of delay. *Sokol Crystal Prod., Inc. v. DSC Commc'ns Corp.*, 15 F.3d 1427, 1430 (7th Cir. 1994) (rejecting statute of limitations defense under Wisconsin UTSA even though plaintiff had "concerns and suspicions" before the limitations period).

> Knowing that Respondents were seeking FDA approval in the United States, Medytox also filed a lawsuit against Daewoong in California Superior Court in June 2017. *See Medytox Inc. v. Daewoong Pharmaceuticals Co., Ltd.*, Case No. 30-2017-00924912-CU-IP-CJC (Cal. Super. Ct., Orange Cty. 2017). That claim was subsequently stayed on *forum non conveniens* grounds in favor of litigation in Korea, which Medytox commenced in October 2017, *see* Seoul Central District Court Case No. 2017Ga-Hap574026, shortly before Medytox filed a citizen petition with the US FDA in December 2017, *see* RX-1880C (FDA Citizen Petition). Approximately thirteen months later, when the commercial launch of Jeuveau became imminent and the corresponding threat of injury to the US domestic industry thus became "substantive and clearly foreseen," *Rubber Resins Comm'n Op.* at 64, Complainants filed their Section 337 Complaint, *see* CX-2612C (HH Jung RWS) at Q/A 7. Thus, even under a three-year limitations period, Complainants' claims are timely.

Compls. Br. at 274–76 (footnote omitted).

The Staff argues, in part:

> Respondents assert that the trade secret misappropriation claim is time-barred because it accrued more than three years before January 25, 2019, when Complainants filed the Complaint. RPB at 193. According to Respondents, Medytox has been aware of Daewoong's possession of a Hall A strain since at least 2014, and admits it "[ ]." CX-2573.52 (Medytox's Responses to Daewoong's 1st Set of ROGs to Medytox) at ROG No. 33. The '418 patent (RX-3330) is issued to Daewoong and "(1) describe[s] experiments comparing the effects of Allergan's BTX-A-1 (BOTOX®) and Daewoong's BTX-A-2 (DWP450), respectively; and (2) identif[ies] the *Clostridium botulinum* strain in each of the two products as a type A Hall strain." RPB at 194. Respondents argue that if the '418 patent is deemed not to provide constructive notice, then Medytox's admission that as of April 2015, it had actual suspicions about Daewoong's strain, should trigger constructive notice. RPB at 195. April 2015 was when Medytox's CEO, Dr. Hyun Ho JUNG, attended a botulinum toxin conference in Dubai, where two Korean doctors gave a presentation on Daewoong's DWP-

> 450 product. Furthermore, Respondents argue, Allergan had constructive notice no later than December 2015 [
>
>]. RPB at 196, citing RX-1655C.4 [ ] (Dec. 15, 2015). Thus, according to Respondents, under the three-year statute of limitations set by the Defend Trade Secrets Act and the Uniform Trade Secrets Act, Medytox should have brought an action no later than April 2018 and Allergan, no later than December 2018. RPB at 193.
>
> Tellingly, Respondents detail a lengthy timeline of events that starts on April 8, 2016, when Medytox filed a private criminal petition with the Seoul Metropolitan Police against two former Medytox employees. RPB at 7–12. Respondents acknowledge that in January 2017, Medytox initiated criminal proceedings against BK Lee and in June 2017, initiated litigation against BK Lee, Daewoong, and Evolus. Yet, none of the actions toll the statute of limitations, according to Respondents, since these earlier actions are not a predicate to the filing of a Section 337 complaint at the Commission. RPB at 200.
>
> . . .
>
> Furthermore, if Respondents' argument that Complainants' trade secret misappropriation claim is time barred at the Commission due to the statute of limitations succeeds, it is an open invitation to unscrupulous actors to misappropriate trade secrets, wait three years past the point when the trade secret owner has constructive notice, import the offending wares into the United States, and then argue that the Commission cannot exclude the products because the action is time barred. This would be a perverse result that would grant a loop-hole to allow misappropriators to take advantage of the legal system to shield themselves and benefit from their illicit gains.

Staff Br. at 144–46 (footnote omitted).

As complainants correctly point out, section 337 does not itself contain a statute of limitations, or a similar statutory provision. Compls. Br. at 273–74. Furthermore, there is nothing in the record to show that complainants were dilatory in pursuing relief,

or that the underlying allegations of trade secret misappropriation are time-barred under law.

Complainants filed the complaint on January 30, 2019, by which point it was reasonably clear that the FDA would grant approval for the sale of Jeuveau®, which occurred two days later, on February 1, 2019. *See* RX-3167C (KY Kim WS) at Q/A 17. That is, the complaint was filed just days before the precondition for commercial importation.

As such, the complaint was filed prior to the imminent commercial importation of DWP-450. [

], complainants had no reason initially to suppose that the representation was to divert away from any misappropriation of the strain and manufacturing process used by Medytox. *See* Jung Tr. 343. For the same reason, complainants' awareness of Evolus's U.S. clinical trials of DWP-450 should not necessarily have prompted action on complainants' part. *See* RX-3544C (Maltman Email, 07/26/14).

Medytox conducted an investigation in late 2016, *see* CX-0013C (Jung WS) at Q/A 124, through which Medytox learned several important facts. First, Medytox learned that [

], *see id.* at Q/A 137. Second, Chang Woo Suh attended the same university and worked in the same lab as BK Lee, a former Medytox employee. Third, BK Lee had subsequently gone to work for Daewoong. *Id.*; *accord* RX-3159C (Suh WS) at Q/A 58-62. Further investigation by Medytox revealed that prior to leaving Medytox, BK Lee had printed and emailed

himself highly sensitive company documents, which he still retained in 2019. *See, e.g.*, CX-2452C (BK Lee Email, 11/02/07); CX-2453C-59C (BK Lee Email Attachs., 11/02/07). These are facts upon which complainants now rely in this investigation.

At that point, in March of 2017, Medytox appropriately pursued a government investigation of Daewoong. *See* Korean Criminal Case No. 2017-000236; CX-1832 (Decision in Korean Criminal Case); CX-0013C (Jung WS) at Q/A 138. This approach demonstrates diligence, not delay. *Sokol Crystal Prod., Inc. v. DSC Commc'ns Corp.*, 15 F.3d 1427, 1430 (7th Cir. 1994) (rejecting statute of limitations defense under Wisconsin UTSA even though plaintiff had "concerns and suspicions" before the limitations period).

Knowing that respondents were seeking FDA approval in the United States, Medytox also filed a lawsuit against Daewoong in California Superior Court in June 2017. *See Medytox Inc. v. Daewoong Pharmaceuticals Co., Ltd.*, Case No. 30-2017-00924912-CU-IP-CJC (Cal. Super. Ct., Orange Cty. 2017). That claim was subsequently stayed on *forum non conveniens* grounds in favor of litigation in Korea, which Medytox commenced in October 2017, shortly before Medytox filed a citizen petition with the U.S. FDA in December 2017. *See* RX-1880C.

Dr. Jung first heard Daewoong's claim that its DWP-450 product was purified from a wild-type *C. botulinum* expressing BTX type A, in April 2015. However, it is not clear why Medytox should have immediately concluded that Daewoong misappropriated the Medytox BTX strain. Dr. Jung testified that it was not until after he spoke to Dr. Chung Sei Kim at a conference in Dubai in March or April 2016 that he began to have suspicions that Daewoong could have misappropriated Medytox's strain. Jung Tr. 333–

337. His suspicions led him to initiate an internal investigation at Medytox, which eventually led to the investigation of BK Lee and his relationship with Daewoong.

The evidence of record shows that complainants are not time-barred from pursuing this investigation. They have sought relief at the time when it was appropriate, and in no case waited more than three years to do so. With respect to this investigation, the complaint leading to this investigation was filed on January 30, 2019, Notice of Receipt of Complaint, 84 Fed. Reg. 1787 (Feb. 5, 2019), shortly before importation of accused products was expected by complainants to begin.

B. Laches

Laches "occurs when a complainant delays in bringing suit for an unreasonable and inexcusable length of time from when it knew or reasonably should have known of the alleged infringement, and where that delay would cause material prejudice to the respondent." *Certain Network Devices, Related Software and Components Thereof (I)*, Inv. No. 337-TA-944, Comm'n Op. at 26 (July 26, 2016) (EDIS Doc. No. 586600) (*citing A.C. Auckerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1028 (Fed. Cir. 1992) (overruled on other grounds)). "The length of time which may be deemed unreasonable has no fixed boundaries but rather depends on the circumstances." *Auckerman*, 960 F.2d at 1032. Additionally, delay in bringing suit "may be excused by a host of factors." *Hemstreet v, Comput. Entry Sys. Corp.*, 972 F.2d 1290, 1293 (Fed. Cir. 1992); *Auckerman*, 960 F.2d at 1033 ("excuses which have been recognized in some instances," examples of which, in a non-exhaustive list, "include: other litigation, negotiations with the accused, possibly poverty and illness under limited circumstances, extent of infringement, and dispute over ownership of the patent" (internal citations

omitted)). The "extent of infringement" excuse was a basis for the Court of Claims to hold that a plaintiff "could reasonably delay bringing suit until he could determine that the extent of possible infringement made litigation monetarily ripe." *Tripp v. U.S.*, 406 F.2d 1066, 1071 (Ct. Cl. 1969). "The equities may or may not require that the plaintiff communicate its reasons for delay to the defendant." *Auckerman*, 960 F.2d at 1033, *citing* CHISUM ON PATENTS § 19.05(2)(b). Furthermore, the rights owner "may be able to preclude application of the laches defense with proof that the accused infringer is itself guilty of misdeeds towards the [rights owner] — '[h]e who seeks equity must do equity.'" *Personal Audio, LLC v. Apple, Inc.*, 9:09-cv-111, 2011 WL 13134589, at *2 (E.D. Tex. Aug. 23, 2011), *quoting Auckerman*, 960 F.2d at 1038.

Respondents argue, in part:

> To the extent the ALJ determines that there is no fixed limitations period for Section 337 actions, Complainants' claims are barred by the equitable doctrine of laches. The evidence demonstrates that Complainants unreasonably delayed bringing suit, to the substantial prejudice to Respondents. *See, e.g.*, *Wanlass v. General Electric Co.*, 148 F.3d 1334, 1337 (Fed. Cir. 1998) (laches applies where "the plaintiff delayed filing suit an unreasonable and inexcusable length of time after the plaintiff knew or reasonably should have known of its claim against the defendant; and the delay resulted in material prejudice or injury to the defendant") (internal citations omitted).
>
> If Complainants had brought suit in a timely fashion, it would have been feasible for Respondents to take proper measures that would have mooted any (even theoretical) need for an exclusion order to remedy the claimed misappropriation. But, Complainants did not file their Complaint in a timely fashion. As explained *supra* in Section VIII.A.1, Complainants knew or should have known of all material facts they included in the Complaint by 2015, at the latest. Indeed, Complainants admitted that by 2015 they had formed the belief that Daewoong might have stolen

Medytox's trade secrets. *Id.* Complainants had all the information regarding BK LEE's allegedly suspicious activities—including the allegations include in Medytox's Complaint—as early as 2008. Had Complainants filed suit at any time between 2008 and 2015, Respondents would have been able to take corrective measures to avoid any time being excluded from the market.

Solely for the purpose of assessing the effect of Complainants' unreasonable delay here, if one were to assume that Complainants' claims that BK LEE misappropriated their trade secrets were valid, the question would be what, if anything, Respondents could have done to rectify the violation. In 2015 or earlier, with the Daewoong-Evolus partnership still in its nascent phase and a large amount of development work on Jeuveau® still to go, the answer would have been a lot. Respondents could have, for example, licensed a different strain from one of the several commercial providers in the market. *See*, *supra*, Section II.E.d. Respondents also could have designed around any alleged manufacturing process trade secrets and restructured their process to distinguish it from Medytox's process. Most importantly, Respondents could have made these adjustments before investing the years that are needed to obtain FDA approval for their product.

However, rather than file this action in a timely fashion—and without cause for their delay—Complainants waited to sue until after (a) Evolus and Daewoong had expended [ ]; (b) Respondents had started making and importing the product for clinical testing; (c) Respondents had applied for FDA approval based on a specific manufacturing process; (d) it was universally acknowledged that Jeuveau® would in fact be approved; and (e) Respondents had started making large quantities of Jeuveau® for commercial sale in expectation of the imminent approval that in fact came. As a result of Complainants' delay, Respondents have sunk costs both in terms of time and money that they should not have had to and thus have been substantially prejudiced.

Respondents' ability to defend themselves against Complainants' allegations has also been substantially prejudiced by Complainants' delay: memories have faded; witnesses have become unavailable; and documents have

> become unavailable. In short, through their delay Complainants have both impaired Respondents' ability to disprove their claims and have—in the event of an exclusion order—maximized the harm to Respondents and all but eliminated their ability to mitigate that harm. These are precisely the circumstances in which laches apply.

Resps. Br. at 277–79 (footnotes omitted).

Complainants argue, in part:

> While the Tariff Act permits parties to raise "all legal and equitable defenses" in an investigation, 19 U.S.C. § 1337(c), that does not mean that all defenses known to equity are cognizable in this forum. When considering equitable defenses, "the Commission should weigh the public and private interests at stake, and should consider all equitable defenses in this context." *Certain Apparatus for the Continuous Prod. of Copper Rod,* Inv. No. 337-TA-52, Recommended Determination, 1979 WL 61155, at *51 (Aug. 13, 1979) ("*Copper Rod Recommended Det.*").
>
> It is well established that the defense of laches is not a bar to *prospective* relief in patent cases before the Commission. *See, e.g.*, *id.* at *52 ("[T]he doctrine of laches bars relief for past practices. In a patent suit, the effect of a successful laches defense is merely to withhold damages for infringement prior to the filing of the suit."); *Certain Pers. Watercraft & Components Thereof*, Inv. No. 337-TA-452, Order No. 54 at 2 (Sept. 19, 2001) ("[L]aches as it pertains to patent-based cases does not, as a matter of law, work to curtail the type of prospective relief sought in [Section] 337 cases.") (citing *Certain EPROM, EEPROM, Flash Memory & Flash Microcontroller Semiconductor Devices*, Inv. No. 337-TA-395, Comm'n Op., Supplemental Views of Chairman Bragg at 11, n.65 (July 9, 1998)). On two recent occasions, the Commission has declined a respondent's invitation to upset this longstanding rule, taking no position on the legal issue. *See Certain Lithium Metal Oxide Cathode Materials*, Inv. No. 337-TA-951, Comm'n Op. at 15-16, 2017 WL 11261372, at *9 (Jan. 26, 2017) (citing *SCA Hygiene Prod. Aktiebolag v. First Quality Baby Prod., LLC*, 807 F.3d 1311, 1332 (Fed. Cir. 2015)); *Certain Network Devices, Related Software & Components Thereof (I),* Inv. No. 337-TA-944, Comm'n Op. at 26, 2017 WL 11261371, at *15 (Apr. 19, 2017).

While the Commission has not ruled on the availability of the laches defense in trade secret cases, there is no reason that the approach should be any different. To the extent that the Commission can award only prospective relief in the form of exclusion and cease and desist orders, that relief should be available in a trade secret case on the same terms as in a patent case. *See Philadelphia Extracting Co. v. Keystone Extracting Co.*, 176 F. 830, 831 (C.C.E.D. Pa. 1910); *see also Reclosable Plastic Bags*, Inv. No. 337-TA-22, Comm'n Mem. Op. at 8-9, USITC Pub. 801 (Jan. 1977) (finding that respondent failed to prove laches and stating "Section 337 mandates that once the Commission finds an unfair method of competition or an unfair act in the importation of articles into the United States, it must rectify the situation. There is no requirement that the unfair act be discovered by a certain time. Even if the unfair act is discovered at a late date or reported at a late date by the complainant, the Commission is still free to rectify the situation.").

In any event, Respondents utterly failed to establish that Complainants were dilatory in seeking relief in this forum – in fact the opposite is true because Complainants initiated this Investigation as promptly as was reasonable under the circumstances. *Cf. Wanlass v. Gen. Elec. Co.*, 148 F.3d 1334, 1337 (Fed. Cir. 1998) ("To prove laches, a defendant must show that 'the plaintiff delayed filing suit an unreasonable and inexcusable length of time after the plaintiff knew or reasonably should have known of its claim against the defendant; and . . . the delay resulted in material prejudice or injury to the defendant.'" (quoting *Gasser Chair Co. v. Infanti Chair Mfg. Corp.*, 60 F.3d 770, 773 (Fed. Cir. 1995))); *Cornetta v. United States*, 851 F.2d 1372, 1380 (Fed. Cir. 1988) ("[U]nder Federal Rule of Civil Procedure 8(c), laches is an affirmative defense."). To successfully bring a complaint before the Commission, "a prospective complainant must mobilize information with respect to each element constituting a violation of § 337, one of which is substantial injury or threat thereof to the domestic industry." *Certain Braiding Machines*, Inv. No. 337-TA-130, Unreviewed Initial Determination at 82, USITC Pub. 1435 (Oct. 1983), 0083 WL 851512, at *36 (finding that "complainant has only recently detected 'injury' in the § 337 sense," which excused its delay in filing) ; *accord Certain Agric. Vehicles & Components Thereof*, Inv. No. 337-TA-487, Final Initial & Recommended Determinations at 133, at

*67 (Jan. 13, 2004), *vacated on other grounds sub nom. Bourdeau Bros. v. Int'l Trade Comm'n*, 444 F.3d 1317 (Fed. Cir. 2006).

Even if the ALJ were to entertain an affirmative defense of laches, the question is ultimately not whether Medytox could have brought a legal claim against Daewoong in another forum earlier – and in any event, Medytox did just that. *See Daewoong Pharm. Co.et al*., Inv. No. 2016-004319, Seoul Metro. Police Agency (crim. pet. filed Apr. 2016); *Medytox Inc. v. Daewoong Pharm. Co., Ltd.*, Case No. 30-2017-00924912-CU-IP-CJC (Cal. Super. Ct., Orange Cty. 2017). Rather, the question is when Medytox could have come to *this* forum. The mandate of the ITC concerns unfair acts in connection with importation causing *substantial injury* to domestic industry, or a threat thereof. 19 U.S.C. § 1337(a)(1)(A)(i). To be cognizable, a "threatened injury must be 'substantive and clearly foreseen.'" *Rubber Resins Comm'n Op.* at 64. Complainants sought relief in this forum at approximately the same time that Respondents commenced commercial importation of Jeuveau in early 2019, and so can hardly be held to have unduly delayed.

Respondents inconsistently argue that Medytox somehow should have known of Daewoong's theft of its trade secrets earlier, while simultaneously maintaining that the evidence that Complainants rely on to confirm that fact – all of which was developed in this Investigation – remains insufficient to establish their liability. The earliest Medytox could have even suspected that Daewoong was using its strain was in April 2015, when Hyun Ho Jung heard Daewoong employees state publicly that DWP-450 was manufactured using a "Hall strain." *See* CX-0013C (HH Jung WS) at Q/A 113; CX-0667C (Nabota Slides from Dubai Conference). But even then, mere suspicions are not enough to start the limitations clock. *See ABB Turbo Sys. AG v. Turbousa, Inc.*, 774 F.3d 979, 985 (Fed. Cir. 2014) (rejecting laches defense as inadequate where plaintiff merely "had an inkling that something was amiss").

The next year, in 2016, the undisputed evidence is that Chung Sei Kim told Hyun Ho Jung that he personally isolated Daewoong's strain from soil. *See* CX-0013C (HH Jung WS) at Q/A 118. In his testimony, Chung Sei Kim admitted that he did so, and now has admitted that he was

> deliberately lying with the "intent . . . to feed misinformation to Medytox." RX-3161C (CS Kim WS) at Q/A 143-45. At a minimum, Chung Sei Kim's admitted attempt to deliberately mislead Medytox in 2016, on behalf of Daewoong, defeats any assertion by Daewoong of an equitable laches defense. *See Holmberg v. Armbrecht*, 327 U.S. 392, 396 (1946) ("[F]raudulent conduct on the part of the defendant may have prevented the plaintiff from being diligent and may make it unfair to bar appeal to equity because of mere lapse of time."). It was therefore not until Medytox conducted its investigation starting in late 2016 and 2017 that Medytox came to suspect that the Accused Products were developed using Medytox trade secrets. Only then did the connections between BK Lee, Chang Woo Suh, and Daewoong's strain and development process begin to come into focus for Medytox. Medytox did not sit on its rights; this Investigation was brought timely.

Compls. Br. at 276–80.

The Staff argues, in part:

> Respondents urge that Complainants' claims be rejected based on the equitable principle of laches, due to the alleged "substantial prejudice flowing from" "Complainants' unreasonable delay in bringing suit." RPB at 201. Respondents claim that Complainants should have brought suit no later than 2015, when Medytox formed a belief that Daewoong stole Medytox's trade secrets. Respondents' arguments are unavailing.
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> . . .
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> Respondents' laches theory would be plausibly meritorious if Respondents could have proven that Medytox should have investigated BK Lee in 2008. Aside from some print outs of documents that, according to BK Lee, were for legitimate work purposes, it is entirely unclear what Medytox should have done at that time or what it should have been suspicious of, especially with respect to Daewoong. If Daewoong's tale of isolation of a *C. botulinum* Hall A-hyper strain from the soil in Korea is to be believed, Daewoong did not even have a strain in its possession, much less even a botulinum toxin development project in the works.
>
> . . .

> Respondents again criticize Complainants for allegedly failing to "bring[] this action in a timely fashion[.]" RPB at 202. As discussed in the section VII.A addressing Respondents' statute of limitations defense, *supra*, Respondents are silent as to how the Commission would have had jurisdiction over this trade secret misappropriation matter unless and until Complainants had evidence that the accused products were imported into the United States. In the Staff's view, Respondents' argument that Complainants sat on their rights contradicts the facts.
>
> Finally, as recognized by several courts, including the Federal Circuit, "he who seeks equity must do equity." *Auckerman*, 960 F.2d at 1038; *see also Pei-Herng Hor v. Ching-Wu Chu*, 699 F.3d 1331, 1337 (Fed. Cir. 2012) ("Under the unclean hands doctrine, a plaintiff may be able to preclude application of the laches defense with proof that the defendant was itself guilty of misdeeds towards the plaintiff." (internal brackets and quotations removed)). As such, if the ALJ determines that Daewoong misappropriated one or more of the Medytox BTX strain and the Medytox proprietary manufacturing processes, the ALJ should dismiss Respondents' laches defense.
>
> For at least the reasons discussed herein, the Staff submits that Respondents' laches defense is not viable.

Staff Br. at 146–49.

The administrative law judge finds that the complainants initiated this investigation as promptly as it was reasonable to do so under the circumstances. *Cf. Wanlass v. Gen. Elec. Co.*, 148 F.3d 1334, 1337 (Fed. Cir. 1998) ("To prove laches, a defendant must show that 'the plaintiff delayed filing suit an unreasonable and inexcusable length of time after the plaintiff knew or reasonably should have known of its claim against the defendant; and . . . the delay resulted in material prejudice or injury to the defendant.'" (quoting *Gasser Chair Co. v. Infanti Chair Mfg. Corp.*, 60 F.3d 770, 773 (Fed. Cir. 1995))); *Cornetta v. United States*, 851 F.2d 1372, 1380 (Fed. Cir. 1988) ("[U]nder Federal Rule of Civil Procedure 8(c), laches is an affirmative defense."). To

bring a complaint before the Commission, "a prospective complainant must mobilize information with respect to each element constituting a violation of § 337, one of which is substantial injury or threat thereof to the domestic industry." *Certain Braiding Machines*, Inv. No. 337-TA-130, Unreviewed ID at 82, USITC Pub. 1435 (Oct. 1983), 0083 WL 851512, at *36 (finding that "complainant has only recently detected 'injury' in the § 337 sense," which excused its delay in filing).

Section 337 pertains to importation causing substantial injury to domestic industry, or a threat thereof. 19 U.S.C. § 1337(a)(1)(A)(i). To be cognizable, a "threatened injury must be 'substantive and clearly foreseen.'" *Rubber Resins*, Comm'n Op. at 64. Complainants sought relief in this forum at the approximate time that respondents commenced commercial importation of Jeuveau® in early 2019.

Even if one were to examine the record to see if laches should apply to the underlying claim of trade secret misappropriation, one would find the evidence discussed above in connection with respondents' "limitations" or time-barred defense. There is even further evidence of attempts to distract from the facts underlying Daewoong's trade secret misappropriation. *See, e.g.,* CX-0013C (Jung WS) at Q/A 118; RX-3161C (CS Kim WS) at Q/A 143–45. At a minimum, attempts to mislead would serve to explain any delay, and to defeat an assertion of an equitable laches defense. *See Holmberg v. Armbrecht*, 327 U.S. 392, 396 (1946).

C. Unclean Hands

It has been observed that unclean hands defense is "exceptional," and "one that rarely prevents the grant of the relief that would otherwise be appropriate." *Polk Bros. v. Forest City Enters., Inc.*, 776 F.2d 185, 193 (7th Cir. 1985). The defense is only

available where the alleged misconduct is "directly related to the very issues in litigation," 6 *Callmann* § 23:17, and "when the plaintiff's transgression is of serious proportions," *Dream Games of Arizona, Inc. v. PC Onsite*, 561 F.3d 983, 990–91 (9th Cir. 2009)(quoting 4 *Nimmer on Copyright* § 13.09[B]); *accord Aptix Corp. v. Quickturn Design Sys., Inc.*, 269 F.3d 1369, 1376 (Fed. Cir. 2001)(quoting *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 245 (1933)).

Respondents argue, in part:

> A party is barred from asserting claims when that party's own misconduct "has immediate and necessary relation to the equity that he seeks in respect of the matter of litigation." *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240, 245 (1933). *See also Precision Instrument Mf'g Co. v. Automotive Maint. Mach. Co.,* 324 U.S. 806, 814-15 (1945) (the doctrine "closes the doors" to "one tainted with inequitableness or bad faith relative to the matter in which he seeks relief"). The unclean hands doctrine "necessarily gives wide range" to the judge's "use of discretion in refusing to aid the unclean litigant," *id*. at 815, and has been applied and affirmed at the Commission. *See Certain Semiconductor Chips and Prods. Containing Same*, Inv. No. 337-TA-753, Comm'n Op. at 51-55. A finding of unclean hands may be predicated on a party's "pre-litigation business misconduct." *See, e.g.*, *Gilead Sciences, Inc. v. Merck & Co., Inc.*, 888 F.3d 1231, 1244 (Fed. Cir. 2018). An appropriate sanction for such a finding, in the intellectual property context, is an order rendering the subject intellectual property unenforceable. *Id.*; *Certain Semiconductor Chips*, Inv. No. 337-TA-753, Comm'n Op. at 51-55.
>
> . . .
>
> In this Investigation, there is only one party that has unequivocally misappropriated alleged trade secrets: Medytox, which obtained the alleged [ ], several years before [ ]. [ ] in discovery from the electronic files of [

>], were [ ] technical documents from approximately 2005 reflecting [
>
>]). *See, e.g.*, RX-2430C ([ ]; RX-2431 ([ ]) (collectively "[ ] Documents").

Resps. Br. at 279–83 (footnote omitted).

Complainants argue, in part:

> Respondents argue that even if they are found to have engaged in unfair acts in violation of Section 337, they should nonetheless be permitted to continue to import Jeuveau, and thereby continue to injure the domestic industry, because Medytox allegedly has "unclean hands." Respondents "bear[] the burden of proving by clear and convincing evidence" their unclean hands defense. *In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1374 (Fed. Cir. 2007). Here, Respondents' scattershot allegations – that Medytox purportedly falsified documents or committed some regulatory infractions in Korea, and that Medytox stole [ ] from [ ] – are entirely unproven and completely irrelevant to the misappropriation issues in this case. *See* Order No. 24 at 28 ("Respondents' arguments show that this investigation could be turned away from the alleged misappropriation that is the basis for the Commission's notice of investigation[.]"). Accordingly, this defense should be swiftly rejected.

Compls. Br. at 280.

The Staff argues, in part:

> Respondents assert a litany of allegations, none of which are contained in their Answers to the Complaint, and most of which have no bearing on the substantive issues in this Investigation, to assert that Complainants' claims are barred under the unclean hands doctrine. Once again, Respondents' arguments lack evidentiary support.

Staff Br. at 150.

PUBLIC VERSION

As an initial matter, neither Daewoong's nor Evolus's answer to the complaint and notice of investigation pleaded the unclean hands affirmative defense with any level of specificity. 19 C.F.R. § 210.13(b) ("Affirmative defenses shall be pleaded with as much specificity as possible in the response."); *see* EDIS Doc. ID Nos. 671900 (Daewoong's Answer (Apr. 1, 2019)) at 43–44, 671916 (Evolus' Answer (Apr. 1, 2019)) at 41. It is not clear that Evolus even asserted unclean hands as an affirmative defense in the answer, as the phrase only appears once in the answer and only asserts that the filing of the section 337 complaint is the unclean act. *See* Evolus' Answer at 41 ("Moreover, to the extent these claims were or may be rejected by authorities in South Korea, Complainants' decision to pursue claims at the ITC is evidence of unclean hands which should equitably preclude it from obtaining relief in this Investigation."). Daewoong's answer has a substantively identical sentence.

With respect to the substance of the defense, during fact discovery, Medytox "inadvertently" produced [ ] document pertaining to [

]. *See* RX-2430C ([ ]); RX-2431C ([ ]). [

]. RX-3020C (Jung Dep. Tr. (June 25, 2019)) at 238. Fact discovery closed on July 19, 2019. On October 14, 2019, Medytox notified respondents that Medytox was in possession of [ ] documents,

which Medytox did not produce. Despite this revelation, respondents did not move to compel the production of these documents.

Complainants argue the documents in [ ] files referring to [ ] are dated July 8, 2005, after the formulation for the Meditoxin drug substance was well established and had been submitted to Korean regulatory authorities. *See* Compls. Br. at 284; RX-0797C-RX-0798C ([ ]); RX-2430C-RX-2431C ([ ]). Complainants argue that the following events occurred prior to the dates that appear on the face of the [ ] documents:

- Medytox filed its investigational new drug application with the KFDA with respect to Meditoxin in and around September 2001 – [ ]. *See* CX-0013C (Jung WS) at Q/A 85, 87.
- Medytox received clinical product authorization on April 9, 2002, and approval of its application to commence clinical trials on August 10, 2002. *See* CX-0013C (Jung WS) at Q/A 90-92; CX-0603C ("Safety Effectiveness Evaluation History" from September 17, 2001 to August 10, 2002).
- Following the completion of clinical trials, Medytox submitted its application to the KFDA in October 2004 and received GMP approval for its production facility in November 2004. *See* CX-0013C (Jung WS) at Q/A 65, 97.

See Compls. Br. at 284–85.

The evidence thus shows that the aspects of the manufacturing process at issue in this investigation were independently developed by Medytox and presented to the KFDA before the [ ] documents were even created. *See* CX-0331.64-65 (Aug. 2004 Master Batch Record); CX-0017C (Chang WS) at Q/A 54; CX-0012C (HW Kim WS) at Q/A 60.

Complainants further argue that [

] were not used to develop Medytox's drug substance and that [

]. *See* Jung Tr. 318–20; CX-2612C (Jung RWS) at Q/A 8–12. Complainants argue that the [

], that demonstrate Daewoong's use of trade secrets that originated with and were misappropriated from Medytox. *Compare* RX-2430C ([

]), *and* RX-2431C.11-17 ([

]), *with* CX-2064C.9-10 (BK Lee Email Attach., 11/02/07), *and* CX-2063C (BK Lee Email Attach., 11/02/07); JX-0022C, JX-0017C, JX-0023C, CX-2068C, CX-2063C, CX-2064C.

[

]. *See* CX-0331C (Master Batch Record, Version No. 01); CX-2143C (Batch Prod. & Control Record).

Respondents admit that it is "impossible to know exactly what Medytox had access to at the time," inasmuch as Medytox did not produce the additional [ ] documents. Resps. Br. at 282. Yet, respondents presume that the unproduced documents contain "[

]." *Id*. If respondents are correct as to the contents of the unproduced documents, it would be consistent with their theory that Medytox fabricated or falsified data [ ] documents for submission to Korean regulators. *See* Resps. Br. at 282–83. Yet as "[ ]," respondents rely

on a media report from the Korean press [

]. *Id*. at 209.

Speculation regarding the contents of the documents is inadequate. Nevertheless, respondents further argue, in part:

> Medytox's misappropriation of the [ ] Documents is not an isolated instance of misconduct. For example, while Medytox CEO Dr. JUNG testified at the hearing that it was merely "a mistake in terms of documentation" and that Medytox is working to fix the problem, Medytox was caught by the Korea FDA fabricating product serial numbers so as to circumvent a recall order from regulators, and in doing so misrepresented the efficacy and expiration dates of the products. *See* Hearing Tr. 325:5-326:8. On February 19, 2020, it was reported that Korean prosecutors had indicted Medytox's Head of Manufacturing (unnamed) for manufacturing products that fall outside the accepted efficacy range and fabricating manufacturing records. The prosecutors and the Korea FDA are reportedly investigating additional misconduct, including manufacturing final drug products with unapproved experimental drug substance and fabricating testing data to obtain regulatory approval in Korea, with the investigation reportedly being focused on the Medytox CEO and key executives' involvement. These allegations are not only relevant to unclean hands, but also are directly relevant to whether there was even a finalized manufacturing process worthy of being a trade secret. The Commission should not reward Complainants with an exclusion order when the legitimacy of Medytox's own process is clouded with doubt.

Resps. Br. at 283–84 (footnote omitted).

Complainants argue that respondents' allegations concerning Medytox's purported regulatory infractions are baseless and that respondents have not even identified a law or regulation that would make the supposed misconduct wrongful. *See* Compls. Br. at 287–88 (citing, *inter alia*, Jung Tr. 325–326; CX-2610C (Chang RWS) at

Q/A 17). It is further argued that in addition to being unproven, these allegations have no place in this investigation because these matters are "governed by distinct bodies of law that provide their own separate remedies for misconduct." Compls. Br at 287 (citing, *inter alia*, *Scherer Design Grp., LLC v. Ahead Engineering LLC*, 764 F. App'x 147, 152-53 (3d Cir. 2019) (rejecting unclean hands defense where plaintiff's alleged violation of state privacy laws was unrelated to its trade secret misappropriation and other claims)).

The administrative law judge finds that uncorroborated reports of Medytox engaging in misconduct have no bearing on the substantive issues in this investigation or the ability of complainants to be afforded relief. Furthermore, even a showing that at some point in the past Medytox failed to adhere to, or violated, a regulatory requirement would not necessarily preclude Medytox today from being a complainant in a section 337 investigation. *See Aptix Corp. v. Quickturn Design Sys., Inc.*, 269 F.3d 1369, 1376 (Fed. Cir. 2001) ("[W]here the misconduct has ceased and the right claimed in the suit did not accrue because of it, the misconduct will be held to be collateral and not to defeat the right to affirmative relief." (quoting McClintock on Equity § 26 (2d ed. 1948))).

X. Recommended Determination

A. Limited Exclusion Order

The Commission has "broad discretion in selecting the form, scope and extent of the remedy." *Viscofan, S.A. v. U.S. Int'l Trade Comm'n*, 787 F.2d 544, 548 (Fed. Cir. 1986). When a violation of section 337 is found, the Commission may issue either a limited exclusion order, directed against products manufactured by or on behalf of named parties found in violation, or a general exclusion order, directed against all infringing products. *See* 19 U.S.C. § 1337(d). A certification provision may be appropriate to

minimize the possibility that any non-covered products will be excluded from entry. *See Certain Digital Televisions and Certain Prods. Containing Same and Methods of Using Same*, Inv. No. 337-TA-617, Comm'n Op. at 11 (April 10, 2009) (EDIS Doc. ID No. 401694).

Complainants argue, in part:

> The Commission should issue a limited exclusion order that excludes from the United States the Accused Products as defined in the Notice of Investigation – namely, all BTX products manufactured by Daewoong, including DWP-450, Jeuveau®, and products containing or derived from DWP-450 or the manufacturing process used to manufacture DWP-450 – with respect to both named Respondents, Daewoong and Evolus, and their affiliated companies, parents, subsidiaries, licensees, and others. Such exclusionary relief is the default remedy that Congress intended for Section 337 violations. 19 U.S.C. § 1337(d)(1); *Spansion v. Int'l Trade Comm'n*, 629 F.3d 1331, 1358–59 (Fed. Cir. 2010). The Commission has held that "[t]he duration of an order in a trade secret misappropriation case is set as the time it would have taken to independently develop the trade secrets." *Rubber Resins*, *Comm'n Op.* at 82 (citing *Railway Wheels Comm'n Op.* at 8-9). When multiple trade secrets are at issue, the remedy may be determined by considering the trade secrets together. *See, e.g., Certain Processes for the Manufacture of Skinless Sausage Casings and Resulting Prod.*, Inv. No. 337-TA-148, 337-TA-169, Comm'n Op. at 19 (Nov. 26, 1984) ("*Sausage Casings Comm'n Op*.").
>
> The evidence established that Respondents misappropriated Medytox's BTX strain as well as certain of Medytox's proprietary information used in its BTX manufacturing process. *See* Sections IV-V. As explained above, Medytox's BTX strain was derived from the Hall A-hyper strain, which is known to have special characteristics making it especially valuable and desirable for commercial production. *Id.; see, e.g.,* CX-0010C (Pickett WS) at Q/A 51, 64-103, 112-13. Medytox's Hall A-hyper BTX strain was not ascertainable and was not independently available to Daewoong for commercial exploitation, nor was any other Hall A-hyper strain readily

available to Daewoong in the time period at issue here. *Id.* at Q/A 51, 64-109, 116-17, 123-82. Whether or not another Type A strain had been available and even if the genetic sequence of Medytox's BTX strain was known, Daewoong could not have engineered it to obtain Medytox's specific BTX strain under *any* timeline. *Id.* at Q/A 51, 64-103, 112-13; *see also supra* at Section IV.A.7, IV.B. Respondents therefore could not have independently developed and manufactured the Accused Products absent their misappropriation of Medytox's BTX strain. Accordingly, an exclusion order for an indefinite period covering all products manufactured from Medytox's strain, or any strain derived from it, should issue against both Respondents. *Id.* at Q/A 51, 53; CX-0018C (Malackowski WS) at Q/A 204.

Although an exclusion order with an indefinite period has not previously been issued by the Commission, such as exclusion order is justified and necessary in order to equitably address the misappropriation of the particular trade secret at issue: Medytox's specific, commercially-viable Hall-A hyper BTX strain.

. . .

An exclusion order of indefinite duration thus is appropriately and narrowly tailored to remedy the precise violation presented by Respondents' misappropriation of Medytox's specific BTX strain. Indeed, this exclusion order addresses only those products containing or derived from Medytox's specific BTX strain, and would not prohibit Respondents from independently developing BTX products with a different BTX strain that they are able to independently acquire or license, and without reliance on the misappropriated trade secrets. *See, e.g,* Hr'g Tr. (Resps. Opening Statement) at 99.

With respect to misappropriation of Medytox's manufacturing process, the evidence has shown that Respondents saved at least 21 months of time by developing their process from Medytox's proprietary process information. CX-0018C (Malackowski WS) at Q/A 205; CX-0010C (Pickett WS) at Q/A 320-25. As discussed at greater length above, Respondents' estimate that it would have taken a mere 3-6 months is based upon a flawed timeline that relied upon the availability of Medytox's misappropriated information. *See* Section V.A. Accordingly, independent of the indefinite limited exclusion

> order based on misappropriation of Medytox's strain, a limited exclusion order of at least 21 months should issue against both Respondents for any products that are made using the misappropriated Medytox information, including the Accused Products, to offset the unlawful advantages obtained and the harm caused by Respondents' unfair acts. CX-0018C (Malackowski WS) at Q/A 205; CX-0010C (Pickett WS) at Q/A 320-25. Of course, since both the strain and manufacturing process were misappropriated, the exclusion order should be indefinite. *Railway Wheels Comm'n Op.* at 8.
>
> No grace period is required before implementing the LEO referenced here. There are several alternative products on the market available to physicians and patients, including BOTOX®, and, as discussed in more detail in Section VI.C. above, the nature and administration of the BTX products at issue permit physicians and patients to easily switch between products. CX-0018C (Malackowski WS) at Q/A 169-74, 185-89, 207; *see generally id.* at Q/A 112-97; CX-2604C.4-10 (Malackowski WS Errata).

Compls. Br. at 290–93.

Respondents argue, in part:

> The Commission has the authority to tailor LEOs to mitigate harm to the public interest. *See Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1360 (Fed. Cir. 2010) (discussing historical application of the public interest factors). Any remedial order that should issue in this Investigation should have an exemption for any products imported for design-around development, testing, and FDA regulatory compliance. Such activities are not importations for consumption and would not harm Complainants, since they would not result in commercial sales. *See Certain Devices for Connecting Computers via Tel. Lines*, Inv. No. 337-TA-360, Comm'n Op. at 7-10 (Nov. 18, 1994). Moreover, in patent investigations, importations for FDA clinical trials would not be subject to any remedial order, as they are exempt from infringement, and a similar exemption should be made here. *See* 35 U.S.C. § 271(e)(1). These activities are regularly carved out from remedial orders, and such carve-outs can be necessary, as here, to avoid interfering with legitimate trade. *See, e.g., Certain Magnetic*

Data Storage Tapes and Cartridges Containing the Same, Comm'n Op. at 132 (Apr. 2, 2018).

Contrary to Staff's contention, the availability of advisory opinions from the Commission is not adequate. Requiring Respondents to seek an advisory opinion before importation of a design-around product for FDA regulatory compliance is backwards and punitive, because Respondents need FDA approval of a redesign before it could be imported for commercial sale and, indeed, before Respondents could seek an effective advisory opinion. Under Staff's proposal, Respondents would have to obtain a new advisory opinion for every modification needed during the clinical trial period. This potentially repeated delay is not an efficient use of party or Commission resources and not necessary to protect Complainants.

Finally, to the extent that a violation is found based solely on injury or threat of injury to Complainants' alleged domestic industry in MT10109L, any remedy should include a reporting requirement to ensure that Complainants continue their alleged domestic industry activities in the United States. If Complainants later abandon those activities for business or regulatory reasons, remedies would no longer be appropriate, as there would be no domestic industry to protect. *See Certain Variable Speed Wind Turbines & Components Thereof, Inv.* No. 337-TA-376, 1996 WL 1056209, at *11, Comm'n Op. at 24-26 (Sep. 23, 1996) ("*Wind Turbines*"). The record shows that [

], making a reporting requirement necessary in this context. RX-3158C.11-12 (Mulhern WS) at Q/A 53-54; RDX-0001C.5 (Mulhern Demonstrative); RX-0742C ([

]); Hearing Tr. 449:19-450:23; *Certain Strontium-Rubidium Radioisotope Infusion Systems, and Components Thereof Including Generators*, Inv. No. 337-TA-1110, ID/RD at 172-73 (Aug. 1, 2019) (recommending reporting requirement when alleged domestic industry product is pending FDA approval) (Commission found no violation on review); *Wind Turbines* at 24-26. Even if MT10109L is approved by the FDA, it is unclear whether domestic activities in MT10109L R&D will continue, making a reporting requirement necessary in that event as well.

. . .

Complainants' request for an indefinite exclusion order for misappropriation of the strain is unprecedented, contrary to the evidence and barred by case law. It must be rejected. Complainants have introduced no evidence at all of the time it would have taken to independently develop the strain. They have therefore failed to carry their burden of proving that a remedy of any duration is warranted, let alone the extreme remedy of permanent exclusion. Plainly, it would not take forever (i.e., be impossible) to independently develop an equivalent to the Medytox's strain, and Complainants have provided no evidence to support this absurd proposition.

The reason that Complainants have not offered evidence to support any duration of independent development is because it is undisputed that in 2010 Daewoong had before it an offer on the table from [

]. CX-2180C.10 (Comprehensive Report on BTA Development Project); CX-2523C.29-30 (Chang Woo SUH Dep. Tr. Vol. 2 at 115:11-117:12); RX-3159C.29-30 (Chang Woo SUH WS) at Q/A 31-34. In particular, the offer—[

]. CX-2180C.10-11 (Comprehensive Report on BTA Development project). [

]. *Id.* at 11. [

]. The time to independently develop a strain was therefore zero or, at most, the few months it would have taken Daewoong [

]. The duration of any exclusion order must be *de minimis* or at most a few months.

There were numerous other independent development opportunities aside from [ ], which further confirm that the independent development period

would have been minimal. The Hall A-Hyper strain and other commercially viable strains were in 2010 and are today available for purchase on the open market. RX-3163C.6 (Singh WS) at Q/A 14-17; RX-3164C.45-47 (Wilson WS) at Q/A 164-70; RX-3166C.15-25 (Sullivan WS) at Q/A 85-136; RX-3159C.29-30 (Chang Woo SUH WS) at Q/A 29-36. In fact, the record reflects that a [

]. CX-2614C.11 (Declaration of Metabiologics, Inc.); RX-3166C.16 (Sullivan WS) at Q/A 89. Complainants' expert, Dr. Pickett, speculates that additional consideration was paid, but has no evidence to support such speculation even though [

]. Similarly, in 2007 and 2010, [

]. *Id.* at 18 (Q/A 105). Dr. Pickett [

]. Hearing Tr. 403:19-22; 407:23-408:2. And, he also conceded that the Hyper strain is not needed to produce a successful commercial product; indeed multiple successful commercial companies, including Ipsen, Merz and Hugel use strains other than the Hall A-Hyper. Hearing Tr. 405:11-407:1. Because Respondents could simply buy an alternative strain on the open market, the alleged misappropriation of Medytox's strain would not have accelerated Jeuveau® to market.

Staff incorrectly suggests that the commercial availability of the strain can be addressed by stating in the exclusion order that Respondents are not barred from selling products using a different botulinum strain. SPB at 111 n.67. First, the law is clear that the duration of the exclusion order can extend only as long as the period of independent development, which here is zero given the commercial availability of the strain and the open offer to Daewoong from MedExGen. Second, Staff's suggestion ignores that Respondents have spent nearly a decade obtaining FDA approval that is specific to their *botulinum* strain and are therefore "locked in" to using that strain or being off the

> market. It is simply not true that a new strain produced today could be used as a substitute for Daewoong's current strain.

Resps. Br. at 284–91 (footnotes omitted).

The Staff argues, in part:

> If a violation of Section 337 is found, the evidence supports a limited exclusion order as to those entities involved in the sale for importation, importation, and sale after importation of the accused products for which a violation is found. For the accused products, these would include both named Respondents, Daewoong and Evolus. CPB at 217–18. In addition, the standard language in Commission limited exclusion orders addressed to affiliated companies, parents, subsidiaries, and others should be included.

Staff Br. at 153.

In a trade secret misappropriation investigation, "[t]he duration of an order in a trade secret misappropriation case is set as the time it would have taken to independently develop the trade secrets." *Rubber Resins*, Comm'n Op. at 82; *Sausage Casings*, Comm'n Op. at 22 ("The facts of this investigation, particularly the fact that the misappropriation involved an actual theft of trade secrets, support the conclusion that Viscofan should not be credited with the time between the misappropriation and the entry of the Commission's remedial order.").

With respect to any violation regarding the misappropriation of the Medytox BTX strain, the evidence shows that the Medytox BTX strain is genetically unique and, even if the full genomic sequence is known by others, it could not be used to duplicate a *C. botulinum* strain capable of commercial use to produce the 900 kDa BoNT complex. CX-0010C (Pickett WS) at Q/A 51, 64–103, 112–13. Respondents assert that the Hall A-hyper strain was widely distributed and available. However, the evidence demonstrates

that was not the case, as shown by Daewoong's own failed efforts to obtain a commercially viable *C. botulinum* strain.

Nevertheless, the record shows that although difficult, it is not impossible to obtain a commercially viable strain through legitimate means. Furthermore, an exclusion order of indefinite duration may be unprecedented, and could put a heavy burden on those charged with enforcing it.

As discussed in detail above, in over three years of trying, Daewoong made inroads was not able to obtain a commercially viable strain. Furthermore, even after obtaining its strain, it took [ ] for Medytox to develop its strain along with a related manufacturing process that would carry a commercial product all the way through regulatory approval. Thus, the duration of a limited exclusion order should exceed those periods of time, and also avoid uncertainties in the future that are unaccounted for in the record. Consequently, the administrative law judge recommends that the duration of a limited exclusion order be 10 years.

If the misappropriation of the Medytox manufacturing process is considered independently, the administrative law judge finds that the duration of the limited exclusion order against accused products manufactured using the asserted Medytox proprietary manufacturing processes should be for a period of at least 21 months from the time of issuance of the exclusion order. *See* CX-0018C (Malackowski WS) at Q/A 205; CX-0010C (Pickett WS) at Q/A 320–25.

B. Cease and Desist Order

The Commission may issue cease and desist orders to respondents found to have violated section 337 in addition to, or instead of, an exclusion order. *See* 19 U.S.C. §

l337(f)(1). Under Commission precedent, cease and desist orders are warranted with respect to respondents that maintain commercially significant U.S. inventories of the infringing product. *See, e.g., Certain Laser Bar Code Scanners and Scan Engines, Components Thereof and Products Containing Same*, Inv. No. 337-TA-551, Comm'n Op. at 22–23 (June 14, 2007) ("The Commission generally issues a cease-and-desist order only when a respondent maintains a commercially significant inventory of infringing products in the United States."); *Certain Recordable Compact Disks and Rewritable Compact Disks*, Inv. No. 337-TA-474, Comm'n Op. at 104 (Feb. 5, 2007) ("Under Commission precedent, cease and desist orders are warranted against respondents with significant inventories of infringing goods in the U.S.").

Complainants argue, in part:

> A CDO against Evolus is appropriate based on the Commission's longstanding policy to issue a CDO against any respondent that maintains a commercially significant U.S. inventory of infringing articles. *See, e.g.*, *Certain Protective Cases*, Inv. No. 337-TA-780, Comm'n Op. at 28, 2012 WL 5874344, at *13 (Nov. 19, 2012) ("The Commission generally issues cease and desist orders 'when there is a commercially significant amount of infringing imported product in the United States that could be sold so as to undercut the remedy provided by an exclusion order.'"). The evidence, including publicly available market data and internal records from Evolus and Daewoong, has shown that a CDO is warranted because Evolus has imported into and maintains in the United States commercially significant inventories of Accused Products. JX-0139C (Importation and Inventory Stipulation); CX-2429C (Evolus June Forecast); CX-2417C ("Summary 6.7.19" tab); CX-0924C (Evolus FUSE Discussion - Updated long term forecast dated March 2019). It is undisputed that these inventories are comprised of regular, commercial-quality products to be sold in the normal course of business. At year-end 2019, Evolus held a U.S. inventory of [ ] 100-unit vials of Jeuveau for commercial use in the U.S., which Respondents stipulated had an imported value of

[ ]. JX-0139C (Importation and Inventory Stipulation). If sold at the [ ], or at its present $610 list price, the value of these vials would be between $33 and $54 million. *Id.*; Hr'g Tr. (Moatazedi) at 917:4-8; CX-2429C (Evolus June Forecast); *see also* CX-0018C (Malackowski WS) at Q/A 210-211; CX-2604C.11 (Errata). Evolus's actual U.S. inventory at year-end 2019 was higher than the projected closing inventory of [ ] vials. JX-0139C (Importation and Inventory Stipulation); CX-2429C (Evolus June Forecast).

. . .

The quantity and expected revenue value of Evolus's on-hand inventory of Jeuveau renders it commercially significant. For example, as Mr. Malackowski estimated, the [ ] vials on-hand reported in June 2019 was enough to satisfy [ ] of the units Evolus expected to sell from July 17, 2019 until the end of 2019, and Evolus' expected inventory on hand near the October 2020 target date will be enough to satisfy [ ] of remaining demand in 2020. *See* CX-0018C (Malackowski WS) at Q/A 208; CX-2604C.10-11 (Errata).

. . .

In addition to the CDO against Evolus, a CDO against Daewoong is warranted for several reasons. First, Daewoong and Evolus entered into a contractual arrangement in their license and supply agreement that demonstrates Daewoong's intent for its Accused Products to enter the United States market and [ ]. *See* JX-0008C.7-8, 11 (Daewoong-Evolus License and Supply Agreement). Daewoong further [ ] set forth in the agreement. *Id.* at JX-0008C.14-15, 43-44. Moreover, Daewoong [ ], pursuant to its license and supply agreement with Evolus. *See id.* at JX-0008C.24 (discussing the responsibilities and membership of a Joint Steering Committee for the Accused

Products); *see also id*. at JX-0008C.22-23, 42-52. For example, Daewoong [

]. *Id*. at JX-0008C.24.

Second, Daewoong has taken multiple steps to provide itself with means by which it can manufacture and sell its Accused BTX Products in the United States other than through Evolus. In their license and supply agreement, Daewoong granted to Evolus [

]. *Id.* at JX-0008C.9 (Daewoong-Evolus License and Supply Agreement). This [

]. CX-0903C.2 (Attachment to email titled "Alphaeon, Tx Toxin Update"); CX-0876C (Letter from Moatazedi to S.H. Joon, CEO of Daewoong). Rather than Evolus, Alphaeon's new subsidiary, AEON Biopharma, will develop these new therapeutic treatment indications. CX-0843C.2 (Nabota Business Division Weekly Work Report (September 1, 2018)); CX-0904C.2 (Attachment to email titled Alphaeon, Aeon Biopharma Process). A CDO against Daewoong–over which the Commission has personal jurisdiction–is thus required to ensure that Daewoong does not engage in acts that would "undercut the remedy provided by an exclusion order," including but not limited to marketing and sales of the Accused Products, and aiding and abetting other entities in the importation, sale for and after importation, transfer (except for exportation), or distribution of the Accused Products, in the United States through Evolus and these other means. *Certain Laser Imageable Lithographic Printing Plates*, Inv. No. 337-TA-636, Initial Determination at 102, USITC Pub. 4204, 2010 WL 5176686, at *81 (Dec. 1, 2010); *Railway Wheels Comm'n Op*. at 5, 9, n. 3; *see also Certain Dental Implants,* Inv. No. 337-TA-934, Comm'n Op. at 65 n.37, 2016 WL 11603664, at *37, n.37 (May 11, 2016.

. . .

Finally, as Mr. Malackowski and Dr. Pickett explained, to prevent Respondents from undercutting the effect of the LEO, the CDOs should also prohibit

> Respondents from continuing to use and benefit from Biologics License Application ("BLA") No. 761085, which covers the Accused Products manufactured using the misappropriated BTX strain and the misappropriated manufacturing process. CX-0018C (Malackowski WS) at Q/A 213; CX-0010C (Pickett WS) at Q/A 129-82; *see also* CX-0010C (Pickett WS) at Q/A 129-82. The BLA is specific to both the misappropriated strain and manufacturing process. Thus, Respondents should be prohibited from making any further use of the BLA in addition to the proprietary strain and manufacturing process information misappropriated from Medytox.

Compls. Br. at 293-98.

Respondents argue, in part:

> As Staff acknowledges, Daewoong has no domestic inventory and no domestic activities, so no cease and desist order should issue as to Daewoong. SPB at 113; Stipulation of Material Facts Relating to Importation and Inventory at ¶ 5; Prehearing Tr. 12:12-23; CX-1794C.23 (Daewoong's Responses & Objections to Staff's 1st Interrogatories) at No. 6; *see also Certain Integrated Repeaters, Switches, Transceivers, & Prods. Containing Same*, Inv. No. 337-TA-435, USITC Pub. No. 3547, Comm'n Op. at 27 (Aug. 16, 2002) ("[C]omplainants bear the burden of proving that respondent has such an inventory. Because complainants failed to sustain their burden, we have determined not to issue a cease and desist order"). Moreover, as noted above, because Daewoong does not participate in the importation or sale after importation of the accused products, Complainants will be unable to satisfy the importation requirement or show that there is a basis for a finding of violation by Daewoong.
>
> As for Evolus, Complainants have not met their burden to show that Evolus maintains commercially significant inventories of infringing products in the United States. *See Certain Light-Emitting Diodes & Prods. Containing Same*, Inv. No. 337-TA-512, Comm'n Op. at 8 (Apr. 14, 2008) (declining to issue CDO where inventory was owned and maintained by third parties). The Commission has found inventories "commercially significant" based on the absolute value of the inventory or based on a comparison between the quantity of inventory and the volume of the product at issue sold or imported over

> time. *See Certain Optoelectronic Devices for Fiber Optic Commc'ns, Components Thereof, & Prods. Containing Same*, Inv. No. 337-TA-860, Comm'n Op. at 36-37 (July 16, 2014*); Certain Electronic Digital Media Devices & Components Thereof*, Inv. No. 337-TA-796, at *73-74, Comm'n Op. at 106-08 (Sep. 6, 2013).
>
> Complainants have not proved that Evolus has a commercially significant inventory and, accordingly, no cease and desist order should issue against Evolus. To the extent that a CDO should issue against any respondent, it should have the same limitations as any LEO that the Commission may issue.
>
> Moreover, Respondents agree with Staff that the ALJ should reject Complainants' request that a cease and desist order require Evolus to forfeit its BLA or otherwise be precluded from selling under the BLA it obtained for Jeuveau®. Neither of these measures, even if possible, is warranted here. The Commission is not empowered to compel the forfeiture of a BLA because that is not an unfair act under Section 337 that can be prohibited by a cease and desist order, and the issuance of BLAs is outside the Commission's jurisdiction. *C.f., Certain Hardware Logic Emulation Systems*, Inv. No. 337-TA-383, 1998 WL 223194, at *62, Comm'n Op. at 30 (Apr. 1, 1998) (discussing how the scope of what cease and desist orders can prohibit is defined by Section 337(a) and (f)). Complainants' argument should be rejected.
>
> Complainants' request is also unnecessary to ensure complete relief. A design-around product that does not use any of Medytox's trade secrets would not violate Section 337. Remedial orders should not restrain legitimate trade, and to the extent that Respondents can produce a new product under the same BLA that does not violate Section 337, the importation and sale of that new product would be legitimate. And if the FDA would require Evolus to obtain a new BLA before Respondents can sell a new, non-violating product, this measure provides Complainants with no additional protection. The Commission need not deviate from the standard scope of remedial orders here.

Resps. Br. at 286–88.

The Staff argues, in part:

PUBLIC VERSION

> [T]he Staff agrees that a cease and desist order should be directed to Evolus. The Staff further submits that the duration of any cease and desist order should equal the duration of an limited exclusion order that may issue, with the same reporting requirements and conditions, if any.
>
> The Staff submits that Complainants are not entitled to a cease and desist order against Daewoong.

Staff Br. at 156–57.

The administrative law judge finds that Evolus, as of year-end 2019, maintained a domestic inventory of [ ] vials of 100U of Jeuveau® having an imported value of [ ]. JX-0139C (Stipulation of Material Facts Relating to Importation and Inventory) at ¶ 6. The list price of each 100 unit vial of Jeuveau® is $610; this imputes a list value exceeding [ ] for the domestic inventory of Jeuveau®. RX-3158 (Mulhern WS) at Q/A 222. This is a commercially significant domestic inventory. Thus, a cease and desist order should be directed to Evolus. The duration of the cease and desist order should equal the duration of any limited exclusion order that may issue, with the same reporting requirements and conditions, if any.

However, complainants are not entitled to a cease and desist order against Daewoong because complainants did not provide admissible evidence of the existence of a domestic inventory of any accused product held by Daewoong or its agents.

Regarding complainants' request that any cease and desist order "prohibit Respondents from continuing to use and benefit from Biologics License Application ('BLA') No. 761085, which covers the Accused Products manufactured using the misappropriated BTX strain and the misappropriated manufacturing process", Compls. Br. at 298, the relief requested has not been shown to be within the Commission's cease and desist order practice.

C. Bonding

Where the Commission determines to issue a remedy, section 337 provides that it shall set a bond during the 60-day Presidential review period at an amount "sufficient to protect the complainant from any injury." 19 U.S.C. § 1337(j)(3); 19 C.F.R. § 210.50 (a)(3). The Commission typically sets the Presidential review period bond based on the price differential between the imported or infringing product, or based on a reasonable royalty. *See*, *e.g.*, *Certain Ink Cartridges and Components Thereof*, Inv. No. 337-TA-565, Comm'n Op. at 63 (Oct. 19, 2007) (EDIS Doc. ID No. 286157) (setting bond based on price differentials); *Certain Plastic Encapsulated Integrated Circuits*, Inv. No. 337-TA-315, Comm'n Op. at 45, USITC Pub. 2574 (Nov. 1992) (setting the bond based on a reasonable royalty). However, where the available pricing or royalty information is inadequate, the bond may be set at 100% of the entered value of the accused product. *See*, *e.g.*, *Certain Neodymium-Iron-Boron Magnets, Magnet Alloys, and Prods. Containing Same*, Inv. No. 337-TA-372, Comm'n Op. at 15, USITC Pub. 2964 (May 1996). In addition, it is complainant's burden to establish support for its requested bonding amount. *See*, *e.g.*, *Certain Liquid Crystal Display Devices*, Inv. No. 337-TA-631 ("*LCD Devices*"), Comm'n Op. at 28 (June 24, 2009) (EDIS Doc. ID No. 406905). Should complainant fail to meet its burden, the Commission may determine that no bond should be imposed during the Presidential review period. *Id*.

Complainants argue, in part:

> Here, a 100 percent bond is appropriate. The evidence has shown that Respondents' pricing for the Accused Products continues to evolve, with Evolus's CEO, David Moatazedi stating that Evolus planned to introduce a new pricing program for Jeuveau in [ ], approximately[ ] after Jeuveau launched on the

market in the United States. The evidence further established that Respondents advertise and rely upon their pricing flexibility for Jeuveau, and, as Mr. Moatazedi confirmed at the Hearing. they have followed an [ ] approach in which Evolus has offered discounts on Jeuveau "to compete against the entire Allergan bundle." Hr'g Tr. (Moatazedi) at 915:20-917:11; CX-2419C.2 (Evolus Board slides); *see also* CX-2377C.2 (Evolus Leadership Summit); CX-1708C (Jafar Dep.) at 65:12-66:11, 236:5-11. Accordingly, a bond rate of 100 percent of the value of the price of the Respondents' Accused Products would best serve the purpose of the bonding requirement. CX-0018C (Malackowski WS) at Q/A 214-17; CX-2604C.11 (Errata). The appropriate bond rate would be between [ ] per vial, which, as discussed above, are Evolus's expected net ASP per vial for 2019 with and without discounts for rebates and coupon allowances. CX-0018C (Malackowski WS) at Q/A 214-17; CX-2604C.11 (Errata). Notably, even a bond rate at the high end of this range does not fully match the potential lost profits suffered by Allergan for each lost sale of BOTOX® Cosmetic, which has had a net ASP of [ ] per vial, with a gross profit margin of [ ]. Hr'g Tr. at 917:4-11; CX-0018C (Malackowski WS) at Q/A 210, 217; CX-2596C [ ] at tab "Botox Cx;" CX-2231C.

Bond rates calculated using a price differential or royalty would not adequately accomplish the purpose of the bonding requirement; both are smaller bond rates (of [ ] per vial and [ ] per vial, respectively) that would allow Respondents to sell Jeuveau at a larger gross profit than a 100 percent bond, while causing Complainants to continue to lose market share and profits. *See id*. at Q/A 214-17; CX-2604C.11 (Errata). Moreover, the Medytox/Allergan Agreement, which contains a [ ] for a product being jointly developed by the licensing partners, has not been demonstrated to be a reasonable royalty rate with respect to the Accused Products. JX-0050C.42 (Allergan-Medytox License Agreement). CX-0018C (Malackowski WS) at Q/A 216; CX-2604C.11 (Errata); *see also Certain Variable Speed Wind Turbines & Components Thereof*, Inv. No. 337-TA-641, Recommended Determination on Remedy & Bonding at 7, 2009 WL 3405241, at *3–4 (Aug. 21, 2009) (recommending a bond of 100% because it was not established that the licenses used in

> the calculation accurately represented a reasonable royalty rate).

Compls. Br. at 299–300.

Respondents argue, in part:

> Complainants have the burden to prove that a bond is necessary and, if necessary, support any bond proposal they advance. *See, e.g.*, *Rubber Antidegradants*, Inv. No. 337-TA-533, Comm'n Op. at 40 (Apr. 2008). Given the high burden on complainants, the Commission often sets no bond when complainants fail to provide evidence of the need for or proper rate of bond. *Id.*; *see also Certain Silicone Microphone Packages,* Inv. No. 337-TA-629, 2009 WL 389263, at *134, ID. at 222 (Feb. 10, 2009). Complainants have not established that any bond is necessary in this case, nor have they provided sufficient evidence that a particular bond rate is appropriate.
>
> Given that Complainants have failed to meet their burden in proving that the bond should be based on some price differential or a reasonable royalty (including a 100% royalty rate), the Commission can and should determine that no bond should be imposed during the Presidential Review Period. *See, e.g.*, *Certain Liquid Crystal Display Devices*, Inv. No. 337-TA-631, Comm'n Op. at 28 (June 24, 2009) (EDIS Doc. No. 406905). For these reasons, even if the Commission finds a violation of Section 337, Respondents should not be required to post a bond to continue importing and selling accused products during the 60-day Presidential Review Period.
>
> **Price Differential**. The parties agree that using a price differential to calculate bond is not appropriate here because a sales price comparison cannot be established. CX-0018C.73-74 (Malackowski WS) at Q/A 215-16; RX-3158C.62-63 (Mulhern WS) at Q/A 352, 360-64. A sales price comparison cannot be conducted for numerous reasons. First, MT10109L does not have a price to compare with Jeuveau®. Second, it is unrebutted that [
>
>]. CX-0018C.73-74 (Malackowski WS) at 215-16;

RX-3158C.62-63 (Mulhern WS) at Q/A 353-59. For example, "Customers at the highest level can get an [ ] on BOTOX®. And they also get that [ ]." Hearing Tr. 919:19-22. Thus, even though Evolus has transparent pricing for Jeuveau®, it is not possible to calculate the actual price of BOTOX® Cosmetic. Indeed, Complainants' expert, Mr. Malackowski, could not offer a single bond rate based on price differential. Instead Mr. Malackowski provided ranges—as a means of calculating bond—which has been rejected by the ITC in the past. *See Certain Magnetic Data Storage Tapes and Cartridges Containing the Same (II),* Inv. No. 337-TA-1076, 2018 WL 7350925, at *96, ID/RD at 177-80 (Dec. 19, 2018).

The only unambiguous price comparator based on the evidence of record is the list price. The unrebutted evidence demonstrated that Jeuveau®'s list price of $610 a vial is higher than that of BOTOX®, which is listed at $601 (there is no list price for MT10109L because it is not on the market in the U.S.). Thus, if list price differentials are the appropriate means to calculate bond, then there should be zero bond. RX-3158C.61 (Mulhern WS) at Q/A 357; CX-1705C.31 (David Moatazedi Dep. Desg. at 125:6-17).

Staff, however, proposes that the Commission set a bond of [ ] per 100 unit vial of Jeuveau® purportedly based on price differentials. SPB at 114-16. To reach that amount, Staff compares the average sales price of Botox® Cosmetic with the imputed imported value of a 100 unit vial of Jeuveau®. *Id*. at 114-15. Staff's price comparison is improper. First, as discussed above, the parties' experts agree that it is not possible to compare BOTOX® Cosmetic's average sales price. Second, there is no basis to compare one type of price metric for BOTOX® with an entirely different price metric for Jeuveau®. Staff cites no case law for their novel approach. Rather, because both BOTOX® Cosmetic and Jeuveau® are imported, the proper comparison is either of both products' average sales price, which is not possible here, or both products' imputed imported value. To the extent a price comparison of the products' imputed imported value is appropriate, Complainants have not conducted such analysis, and thus cannot meet their burden. Neither has Staff. Without any evidence comparing the imputed imported values, there should be zero bond.

> **Reasonable Royalty**. The Commission should not set a bond in this case because Complainants have failed to meet their burden. If the Commission believes that a bond is proper, however, Complainants' and Respondents' experts agree that the record supports [ ]. CX-0018C.74 (Malackowski WS) at Q/A 216; RX-3158.62-64 (Mulhern WS) at Q/A 352, 360-64. That rate is supported by [
>
>]. JX-0050C.38 (Allergan-Medytox Agreement). That Agreement is undeniably a comparable license. *See Semiconductor Chips*, Inv. No. 337-TA-432, RD at 7-8 (Oct. 1, 2001) (setting a 10% bond because it was "within the range of royalties obtained by [complainant] from its licensees."); *see also Certain LED Lighting Devices, LED Power Supplies, and Components Thereof*, Inv. No. 337-TA-1081, 2019 WL 7423547, at *23, Comm'n Op. at 38-41 (July 23, 2019). Complainants have not presented any evidence to suggest that the bond amount in the 2013 Allergan-Medytox Agreement is not a reasonable royalty.
>
> Despite this evidence, Complainants try to argue that because it is impossible to compare the ASP of BOTOX® Cosmetic and Jeuveau®, a 100% royalty rate is appropriate. CPB at 222-224. However, such a suggestion ignores that 100% bond should only be used in cases where there is insufficient evidence in the record to determine a reasonable royalty rate. *See Certain Lighting Control Devices Including Dimmers Switches and Parts Thereof*, ITC Inv. No. 337-TA-776, Comm'n Op. on Remedy, the Public Interest, and Bonding at 28 (Nov. 8, 2012). That is not the case here, however, as there is direct evidence of a reasonable royalty rate. *See Certain Digital Photo Frames and Image Display Devices and Components Thereof*, ITC Inv. No. 337-TA-807, Comm'n Op. at 17 (Mar. 27, 2013).

Resps. Br. at 292–95 (footnote omitted).

The Staff argues, in part:

> The amount of such bond must "be sufficient to protect the complainant from any injury." 19 U.S.C. § 1337(j)(3); *see also* 19 C.F.R. § 210.50(a)(3). The Commission typically sets the Presidential review period bond based on the price

> differential between the imported or infringing product, or based on a reasonable royalty. *See*, *e.g.*, *Certain Ink Cartridges & Components Thereof*, Inv. No. 337-TA-565, Comm'n Op. at 63 (Oct. 19, 2007) (EDIS Doc. No. 286157) (setting bond based on price differentials); *Certain Plastic Encapsulated Integrated Circuits*, Inv. No. 337-TA-315, Comm'n Op. at 45, USITC Pub. 2574 (Nov. 1992) (setting the bond based on a reasonable royalty). . . .
>
> . . .
>
> [T]he Staff submits a bond rate of [ ] per 100U vial of Jeuveau should be sufficient to protect Allergan from further injury.

Staff Br. at 157–59.

The administrative law judge finds that, as proposed by the Staff, a bond in the amount of [ ] per 100U vial of Jeuveau® (which reflects the difference in the average sales price of [ ] for BOTOX® Cosmetic in 2018 versus the imputed imported value of a 100U vial of Jeuveau® of [ ] should be imposed during the Presidential review period. *See* CX-2331C [ ] (average sales price of [ ] for BOTOX® Cosmetic in 2018); JX-0139C (Stipulation of Material Facts Relating to Importation and Inventory) at ¶ 6 (Evolus' domestic inventory of [ ] vials of 100U of Jeuveau® having an imported value of [ ]). The imported value assigned by Evolus to its existing inventory of Jeuveau® of nearly [ ] per 100U vial of Jeuveau® is in line with the [ ] price per 100U vial Evolus agreed to pay Daewoong. JX-0008C.43 (Annex B to License & Supply Agreement between Daewoong and Evolus).

A bond rate set at the difference in average sales price between Jeuveau® and BOTOX® Cosmetic would be insufficient to protect the complainant from any injury. Evolus has offered [ ] various discounts that, [ ], give its physician customers [ ]. CX-0018C

(Malackowski WS) at Q/A 165. The list price of Jeuveau® is $610 per vial. RX-3162C (Moatazedi WS) at Q/A 34. Applying a [ ] discount to the list price translates to a price as low as [ ] per vial of Jeuveau®. The list price of a 100U vial of BOTOX® Cosmetic is $601. CX-2231C (Allergan product pricing list). Thus, the maximum difference in sales price between Jeuveau® and BOTOX® Cosmetic is [ ]. If Allergan offers discounts, the difference in the sales price between the products would, of course, be lower. Even if the bond amount were set at [ ], Evolus would be able to post that bond and continue to sell Jeuveau® [ ], and make a gross profit, as its cost of goods would total [ ] (assuming it pays Daewoong [ ] per vial, plus the bond posted per vial). If the bond rate is set at a figure representing the difference in average sales price between Jeuveau® and BOTOX® Cosmetic, Evolus' potential gross profit (and incentive to continue its sales) would be much greater, inasmuch as the bond amount would be lower than [ ]. Thus, the difference in average sales price between Jeuveau® and BOTOX® Cosmetic is not sufficient to protect Allergan from further injury.

The evidence demonstrates that for every [ ] vials of Jeuveau® that are sold, Allergan loses the sale of [ ] vials of BOTOX® Cosmetic. *See*, *e.g.*, CX-2385C (Pricing Analysis); CX-0018C (Malackowski WS) at Q/A 132. By raising Evolus' cost of each vial of Jeuveau® to equal the average sales price of BOTOX® Cosmetic prior to the May 2019 introduction of Jeuveau® in the United States market, a bond rate of [ ] per 100U vial of Jeuveau® should be sufficient to protect Allergan from further injury.

Accordingly, in the event that a violation of section 337 is found, it is recommended that during the Presidential review period, respondents be required to post a bond of [ ] per 100U vial of Jeuveau®.

It is the RECOMMENDED DETERMINATION ("RD") of the administrative law judge that in the event a violation of section 337 is found, the Commission should issue a limited exclusion order, and a cease and desist order. Further, should the Commission impose a remedy that prohibits importation, it is recommended that the Commission subject respondents' importations during the Presidential review period to a bond.

XI. Conclusions of Law

1. The Commission has subject matter, personal, and *in rem* jurisdiction in this investigation.

2. The accused products have been imported or sold for importation into the United States.

3. The complainants have standing in this investigation.

4. Respondents' affirmative defenses neither preclude a finding of violation, nor the issuance of a remedy.

5. It has been shown that Medytox's trade secrets have been misappropriated, causing substantial injury to the domestic industry.

6. The domestic industry requirement has been satisfied with respect to the alleged trade secrets.

XII. Initial Determination and Order

Accordingly, it is the INITIAL DETERMINATION of the undersigned that a violation of section 337 of the Tariff Act, as amended, has occurred in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain botulinum neurotoxin products by reason of the misappropriation of trade secrets, the threat or effect of which is to destroy or substantially injure an industry in the United States.

Further, this Initial Determination, together with the record of the hearing in this investigation consisting of (1) the transcript of the hearing, with appropriate corrections as may hereafter be ordered, and (2) the exhibits received into evidence in this investigation, is CERTIFIED to the Commission.

In accordance with 19 C.F.R. § 210.39(c), all material found to be confidential by the undersigned under 19 C.F.R. § 210.5 is to be given *in camera* treatment.

The Secretary shall serve a public version of this ID upon all parties of record and the confidential version upon counsel who are signatories to the Protective Order, as amended, issued in this investigation.

Pursuant to 19 C.F.R. § 210.42(h), this Initial Determination shall become the determination of the Commission unless a party files a petition for review of the initial determination pursuant to 19 C.F.R. § 210.43(a), or the Commission, pursuant to 19 C.F.R. § 210.44, orders on its own motion a review of the initial determination or certain issues contained herein.

* * *

All ripe, outstanding motions that have not been granted are hereby denied.

To expedite service of the public version, each party is hereby ordered to file with the Commission Secretary no later than July 17, 2020, a copy of this initial and recommended determination with brackets to show any portion considered by the party (or its suppliers of information) to be confidential, accompanied by a list indicating each page on which such a bracket is to be found. At least one copy of such a filing shall be served upon the office of the undersigned, and the brackets shall be marked in bold red. If a party (and its suppliers of information) considers nothing in the initial determination to be confidential, and thus makes no request that any portion be redacted from the public version, then a statement to that effect shall be filed.[28]

DPShaw

David P. Shaw
Administrative Law Judge

Issued: July 6, 2020

[28] Confidential business information ("CBI") is defined in accordance with 19 C.F.R. § 201.6(a) and § 210.5(a). When redacting CBI or bracketing portions of documents to indicate CBI, a high level of care must be exercised in order to ensure that non-CBI portions are not redacted or indicated. Other than in extremely rare circumstances, block-redaction and block-bracketing are prohibited. In most cases, redaction or bracketing of only discrete CBI words and phrases will be permitted.

CERTAIN BOTULINUM TOXIN PRODUCTS, PROCESSES FOR MANUFACTURING OR RELATING TO SAME AND CERTAIN PRODUCTS CONTAINING SAME **Inv. No. 337-TA-1145**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **Initial Determination** has been served via EDIS upon the Commission Investigative Attorney, **Monica Bhattacharyya, Esq.**, and the following parties as indicated, on **August 6, 2020**.

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